

# EXHIBIT F

Exhibit consists of deposition testimony from a Texas state court action, *Ramirez v. Cesar Reyes, M.D., Johnson & Johnson, and Ethicon, Inc.*, Cause No. 2012-CI-18690, in which Ethicon retained Dr. Sepulveda-Toro to defend Ethicon's TVT products against substantially similar allegations as presented in the instant litigation. Any excerpts contained in Ex. F are taken from portions of that deposition which speak to general causation. Because much of Ex. F contains deposition testimony directed at specific causation, that portion of the transcript is not excerpted due to confidentiality concerns. Should the Court desire to examine the entire transcript, Plaintiffs request this be submitted under seal, or some other similarly protective measure.

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CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A	)	IN THE DISTRICT COURT
JENNIFER GALINDO,	)	
	)	
Plaintiff,	)	
	)	438th JUDICIAL DISTRICT
v.	)	
	)	
CESAR REYES, M.D., JOHNSON &	)	
JOHNSON, AND ETHICON, INC.,	)	BEXAR COUNTY, TEXAS
	)	
Defendants.	)	
_____	)	

DEPOSITION OF

JAIME SEPULVEDA, M.D.

DATE: April 8, 2016

TIME: 9:17 a.m. - 5:10 p.m.

GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

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<p>1 APPEARANCES (Continued):</p> <p>2 APPEARING ON BEHALF OF DR. REYES:</p> <p>3 David J. McTaggart, Esq.</p> <p>4 SCOTT, CLAWATER &amp; HOUSTON, LLP</p> <p>5 2727 Allen Parkway, 7th Floor</p> <p>6 Houston, Texas 77019</p> <p>7 dmctaggart@schlawyers.com</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 cause?</p> <p>2 MS. GALLAGHER: Yes, I do, because under</p> <p>3 the rule it says that notice must be given that</p> <p>4 the deposition will be recorded by other than</p> <p>5 stenographic means. It does not say used.</p> <p>6 MR. GOSS: And you refuse to let us go</p> <p>7 forward in the event that we want to record it,</p> <p>8 video it for our own purposes and for no</p> <p>9 purpose to be used at trial?</p> <p>10 MS. GALLAGHER: Yes.</p> <p>11 MR. GOSS: And we've offered you that we</p> <p>12 would not use it for any purpose at trial and</p> <p>13 you refuse to proceed forward, even under that</p> <p>14 condition?</p> <p>15 MS. GALLAGHER: Yes.</p> <p>16 MR. GOSS: Okay. Just for the record, we</p> <p>17 will take this to the Court. In the event that</p> <p>18 the Court determines that we are entitled to</p> <p>19 video it for our own purposes, then we're going</p> <p>20 to ask to come down here and take it again.</p> <p>21 That's all.</p> <p>22 THE VIDEOGRAPHER: This is the end of</p> <p>23 video portion. It's 9:14 a.m.</p> <p>24 THE COURT REPORTER: Raise your right</p> <p>25 hand, please, sir. Do you swear or affirm that</p>
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<p>1 THE VIDEOGRAPHER: We're on the record.</p> <p>2 The witness is not present. Counsel Tim Goss</p> <p>3 has requested the video be turned on for</p> <p>4 objections regarding the video. The time is</p> <p>5 9:12 a.m., and the matter is Jennifer Ramirez</p> <p>6 versus Ethicon, et al. Today's date is April</p> <p>7 8, 2016.</p> <p>8 MS. GALLAGHER: This is Kat Gallagher on</p> <p>9 behalf of Johnson &amp; Johnson, and we have a, and</p> <p>10 Ethicon, and we have a deposition notice for</p> <p>11 Dr. Sepulveda today that was noticed for</p> <p>12 stenographic only. Pursuant to Rule 199.2, we</p> <p>13 object to this going forward by video because</p> <p>14 under Rule 199.2, at least five days prior to</p> <p>15 the deposition, the party must serve on the</p> <p>16 witness and all parties a notice that the</p> <p>17 deposition will be recorded by other than</p> <p>18 stenographic means. We did not get five days</p> <p>19 notice and I object to it going forward by</p> <p>20 video.</p> <p>21 MR. GOSS: And just so I'm clear on your</p> <p>22 objection, you object to us by recording -- you</p> <p>23 object to our recording of the deposition, even</p> <p>24 in the event that we do not intend to use the</p> <p>25 video of the deposition at any trial in this</p>	<p>1 the testimony you are about to give will be the</p> <p>2 truth, the whole truth and nothing but the</p> <p>3 truth?</p> <p>4 THE WITNESS: I do swear.</p> <p>5 THEREUPON,</p> <p>6 JAIME SEPULVEDA, M.D.,</p> <p>7 having been first duly sworn/affirmed to tell the</p> <p>8 truth, the whole truth and nothing but the truth, was</p> <p>9 examined and testified under oath as follows:</p> <p>10 DIRECT EXAMINATION</p> <p>11 BY MR. FREESE:</p> <p>12 Q. Good morning. Good to see you again.</p> <p>13 I'm going to mark Exhibit 1 to your deposition, which</p> <p>14 is the notice of your deposition.</p> <p>15 (Plaintiff Exhibit No. 1 was marked for</p> <p>16 identification.)</p> <p>17 BY MR. FREESE:</p> <p>18 Q. Have you seen that before, sir?</p> <p>19 A. Yes, sir.</p> <p>20 Q. All right, and you were provided a copy</p> <p>21 of it before the deposition?</p> <p>22 A. Yes.</p> <p>23 Q. And you were requested to bring some</p> <p>24 documents?</p> <p>25 A. Yes.</p>

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<p>1 Q. Okay. And did you do so?</p> <p>2 A. Yes, I did.</p> <p>3 Q. And I'm going to mark Exhibit 2 to your</p> <p>4 deposition, which is Ethicon's response to the</p> <p>5 deposition notice.</p> <p>6 (Plaintiff Exhibit No. 2 was marked for</p> <p>7 identification.)</p> <p>8 BY MR. FREESE:</p> <p>9 Q. Have you seen that before?</p> <p>10 A. I see it for the first time now.</p> <p>11 Q. Me showing you now, that's the first time</p> <p>12 you've seen it?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Okay. You don't know what Ethicon</p> <p>15 objected to producing and what it didn't object to</p> <p>16 producing?</p> <p>17 A. Yeah, I'm aware that they objected to my</p> <p>18 1099s.</p> <p>19 Q. Okay, and other than your 1099s, was</p> <p>20 there anything withheld that we requested to be</p> <p>21 brought, other than the 1099s?</p> <p>22 A. Not that, not that I'm aware.</p> <p>23 Q. Okay. So, everything that you have</p> <p>24 looked at and relied upon is either physically in the</p> <p>25 room either in paper form or on a thumb drive?</p>	<p>1 supplemental reliance list that is printed, it says</p> <p>2 April 5, 2005, which I guess was three days ago.</p> <p>3 (Plaintiff Exhibits No. 3 and 4 were</p> <p>4 marked for identification.)</p> <p>5 A. Yeah.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Is that right?</p> <p>8 A. That's right.</p> <p>9 Q. Okay. And is Exhibit 4 your supplemental</p> <p>10 reliance list?</p> <p>11 A. Yes, this looks like my reliance list and</p> <p>12 I would say supplemental reliance list.</p> <p>13 Q. Okay, and do you know sitting here what</p> <p>14 was added or subtracted from your supplemental reliance</p> <p>15 list?</p> <p>16 A. This has articles on, on other, other,</p> <p>17 this has articles on biomechanics, and, as I can see</p> <p>18 just flipping through these, these pages, it has my,</p> <p>19 all the things that I relied that I testified on last</p> <p>20 week.</p> <p>21 Q. Okay. Well, what I'm, what I'm trying to</p> <p>22 find out is, is there a way that I can, without going</p> <p>23 line by line, figure out what it is you added to your</p> <p>24 supplemental reliance list on the 5th of April, three</p> <p>25 days ago?</p>
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<p>1 A. I have, I have made an effort to put</p> <p>2 everything there on the floor and I have my thumb</p> <p>3 drive.</p> <p>4 Q. Okay, my question is, is everything that</p> <p>5 you have reviewed and relied on in this case either on</p> <p>6 the thumb drive or on the floor in paper format?</p> <p>7 A. Yes.</p> <p>8 Q. And the only set of documents that have</p> <p>9 been withheld are your 1099s?</p> <p>10 A. Yes.</p> <p>11 MS. GALLAGHER: And, Rich, just to be</p> <p>12 clear, I don't know if all of the literature is</p> <p>13 on this thumb drive, but I think all the</p> <p>14 case-specific materials are on there. I'm just</p> <p>15 not clear if we loaded up all the literature</p> <p>16 again.</p> <p>17 MR. FREESE: Okay.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. And, Doctor, we were provided a</p> <p>20 supplemental reliance list of yours this week. Did you</p> <p>21 realize that?</p> <p>22 A. Yes.</p> <p>23 Q. So, let me go ahead, and I'm going to</p> <p>24 mark what was referenced to us as your reliance list as</p> <p>25 Exhibit 3, and I'm going to mark as Exhibit 4 your</p>	<p>1 A. No, I've been giving articles that I come</p> <p>2 across but I did bring the articles that are not in</p> <p>3 here.</p> <p>4 MS. GALLAGHER: Rich, I might be able to</p> <p>5 short change this. I think the only thing that</p> <p>6 was added were additional medical records that</p> <p>7 didn't make the original list. I don't believe</p> <p>8 there's any additional articles on there, is my</p> <p>9 understanding.</p> <p>10 MR. FREESE: That's what I'm trying to</p> <p>11 find out.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. So, based on what, what Ms. Gallagher</p> <p>14 said, does that sound accurate to you, Doctor, that the</p> <p>15 only supplement has been additional records?</p> <p>16 A. That sounds accurate.</p> <p>17 Q. And in fairness, this reliance list is</p> <p>18 not prepared by you, is it?</p> <p>19 A. No, initially it's given in a packet,</p> <p>20 although I can tell you that most of these articles I</p> <p>21 read through them through the years.</p> <p>22 Q. I understand. I move to strike that.</p> <p>23 That's not really my question, Dr. Sepulveda. These</p> <p>24 reliance lists, Exhibit 3 and Exhibit 4, are prepared</p> <p>25 by lawyers for Ethicon, not by you, correct?</p>

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<p>1 A. That is correct.</p> <p>2 Q. You didn't sit here at your computer and</p> <p>3 create 70 or 80 pages of single-spaced reliance</p> <p>4 materials?</p> <p>5 A. I did put together the articles, I did</p> <p>6 the research for the articles that are included</p> <p>7 initially on the TVTO summary that is used in this</p> <p>8 case.</p> <p>9 MR. FREESE: Move to strike.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. Not my question, sir. You didn't sit</p> <p>12 here and prepare at a computer your reliance materials.</p> <p>13 That was done by the lawyers, correct?</p> <p>14 A. Yes, on the computer was done by them.</p> <p>15 Q. And then it's attached to your report,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And your testimony is that you</p> <p>19 think over the years you've seen or read most of the</p> <p>20 things on your reliance list?</p> <p>21 A. I would say all of them.</p> <p>22 Q. So you've read all the internal Ethicon</p> <p>23 documents referenced on your reliance list?</p> <p>24 A. I have a binder that has been provided to</p> <p>25 me with the TVTO company documents.</p>	<p>1 A. No.</p> <p>2 Q. Okay. So, one hundred percent of the</p> <p>3 internal documents that you've looked at regarding TVTO</p> <p>4 or any meshes that you testify about are hand selected</p> <p>5 and given to you by Ethicon, correct?</p> <p>6 A. Yes.</p> <p>7 Q. All right, Doctor, we're going to go</p> <p>8 ahead and mark your copy of the -- this is the report</p> <p>9 prepared in this case, is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. All right, I'm going to mark as Exhibit</p> <p>12 5 --</p> <p>13 MR. JORDAN: Can we mark this and get a</p> <p>14 copy of this? I think what we would like to do</p> <p>15 is just mark it so he can have his original</p> <p>16 back and we can replace the copy with the depo</p> <p>17 when we get it. I just want it in the record</p> <p>18 that he brought this and what it is.</p> <p>19 MS. GALLAGHER: Yeah, that's fine, it's</p> <p>20 just because trial is so close we just want to</p> <p>21 get his materials back to him as fast as we</p> <p>22 can.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. So, I'm going to mark as Exhibit 5 the</p> <p>25 documents that Ethicon's lawyers provided to you of the</p>
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<p>1 Q. Okay, and did you bring it here with you</p> <p>2 today?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And do you have a binder of those?</p> <p>5 A. Yes.</p> <p>6 Q. Do you mind grabbing that?</p> <p>7 A. No.</p> <p>8 Q. And would you go ahead and describe</p> <p>9 what's in this binder for me?</p> <p>10 A. It's a, it's a group of, it's a mixed</p> <p>11 group of the history of TVTO, the -- I'm not going to</p> <p>12 read the whole thing.</p> <p>13 Q. That's fine, just a narrative.</p> <p>14 A. But, the summaries of how TVTO was</p> <p>15 developed.</p> <p>16 Q. Okay. And, again, these were internal</p> <p>17 documents that were hand picked by the lawyers for</p> <p>18 Ethicon, is that correct?</p> <p>19 A. They, they were provided to me. I don't</p> <p>20 know what, what method they used.</p> <p>21 Q. Well, the method was, they chose which</p> <p>22 documents to supply to you, correct?</p> <p>23 A. I, I think, I think, yes.</p> <p>24 Q. Okay. And is there any specific internal</p> <p>25 document that you asked them to provide to you?</p>	<p>1 internal records of the company, the binder.</p> <p>2 A. I understand.</p> <p>3 (Plaintiff Exhibit No. 5 was marked for</p> <p>4 identification.)</p> <p>5 BY MR. FREESE:</p> <p>6 Q. Okay. I'll mark as Exhibit 6 your expert</p> <p>7 opinion in the Jennifer Ramirez case.</p> <p>8 (Plaintiff Exhibit No. 6 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. FREESE:</p> <p>11 Q. Is that correct?</p> <p>12 A. Yes. You mean my marked copy?</p> <p>13 Q. Yes, I want to mark your marked copy.</p> <p>14 A. Yes.</p> <p>15 Q. And these are, the pink stickies are</p> <p>16 yours?</p> <p>17 A. Yes.</p> <p>18 Q. In your handwriting?</p> <p>19 A. Yes.</p> <p>20 Q. And there's highlighting here also,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. Generally, what is it that you</p> <p>24 highlighted?</p> <p>25 A. Anything that I, I anticipate that you</p>

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<p>1 would ask me about.</p> <p>2 Q. Okay. Fair enough. And I'm going to</p> <p>3 give it back to you, and I may, I may ask to get it</p> <p>4 back to see what's highlighted and what the notes say</p> <p>5 when I get to that particular page. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. Doctor, I'm going to try to do this in</p> <p>8 just page-flipping order so we can get through this,</p> <p>9 but am I correct that this expert report is virtually</p> <p>10 identical to a number of expert reports that you have</p> <p>11 issued in synthetic mesh litigation lawsuits?</p> <p>12 A. They, the general report, yes.</p> <p>13 Q. The credentials and qualifications would</p> <p>14 be virtually identical?</p> <p>15 A. Yes.</p> <p>16 Q. Okay, and the general opinions that you</p> <p>17 hold about TVT and TVTO and TVTS are all virtually</p> <p>18 identical?</p> <p>19 A. Yes, sir.</p> <p>20 Q. Okay, and then we have some opinions that</p> <p>21 are specific to Ms. Ramirez's case, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Am I correct, like your reliance</p> <p>24 list, that your expert report is not prepared by you</p> <p>25 but rather is prepared by the lawyers for Ethicon?</p>	<p>1 care plan?</p> <p>2 A. If I -- repeat that again, please.</p> <p>3 Q. Yes, sir. There's four pages of, of</p> <p>4 opinions that you have about the life care plan that</p> <p>5 you say you did not prepare.</p> <p>6 A. No, I did not type those, and, and those</p> <p>7 were prepared by the attorney's office and I reviewed</p> <p>8 them.</p> <p>9 Q. Okay, you reviewed the comments?</p> <p>10 A. Yes.</p> <p>11 Q. Did you review any of the underlying</p> <p>12 documents that made up the life care plan?</p> <p>13 A. Yes, I reviewed the documents prepared by</p> <p>14 Mr. Harrell, and I read the deposition of Dr. Elizondo.</p> <p>15 Q. All right, and these are -- were there</p> <p>16 anything other than those two depositions that you</p> <p>17 read?</p> <p>18 A. No.</p> <p>19 Q. Did you read the entirety of the</p> <p>20 depositions?</p> <p>21 A. I, yeah, Elizondo, I read the whole</p> <p>22 thing.</p> <p>23 Q. Were there portions selected for you by</p> <p>24 the lawyers, or did you just, you sat down and read the</p> <p>25 whole deposition?</p>
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<p>1 A. No, that's not correct.</p> <p>2 Q. Okay. So, who actually types this</p> <p>3 report?</p> <p>4 A. I, I did.</p> <p>5 Q. You typed this 66-page report?</p> <p>6 A. I actually did.</p> <p>7 Q. Okay, and how long did it take you to</p> <p>8 type this 66-page report?</p> <p>9 A. I'm going to, I'm going to, I misspoke on</p> <p>10 the, the whole report. The, the part that has to do</p> <p>11 with the life care plan, I did not type that one.</p> <p>12 Q. Okay. So, the life care plan opinion</p> <p>13 starts at page 63 of your report?</p> <p>14 A. Yes, that's correct.</p> <p>15 Q. And you did not type that?</p> <p>16 A. No, I did not type the comments on the</p> <p>17 life care plan.</p> <p>18 Q. Who prepared your comments on the life</p> <p>19 care plan?</p> <p>20 A. The, the attorney's office.</p> <p>21 Q. Okay. Do you know who in the attorney's</p> <p>22 office?</p> <p>23 A. No.</p> <p>24 Q. Okay. Did you actually review any</p> <p>25 underlying records to create the comments in the life</p>	<p>1 A. No, that one I read the whole, whole</p> <p>2 deposition.</p> <p>3 Q. I can look at your reliance list, but</p> <p>4 there are a lot of depositions that are listed here.</p> <p>5 Did you read every one of them?</p> <p>6 A. At some point, I have read them, because</p> <p>7 being this is so long, this is two years, but yes, I</p> <p>8 have read the depositions, and they don't all come, as</p> <p>9 you probably would know, they don't come at one time.</p> <p>10 They come in sequence.</p> <p>11 Q. So, over the period of Ms. Ramirez's</p> <p>12 case, you've read several thousands of pages of</p> <p>13 deposition testimony to form your opinion, correct?</p> <p>14 A. Yes, sir.</p> <p>15 Q. And that would include all of her</p> <p>16 treating physicians?</p> <p>17 A. Yes, all the treating physicians that</p> <p>18 I've been made aware of by the medical records.</p> <p>19 Q. Her deposition, correct?</p> <p>20 A. Two, both of them.</p> <p>21 Q. Three of them. Did you know there were</p> <p>22 three, three installments of her deposition?</p> <p>23 A. No, I read two, two depositions.</p> <p>24 Q. Did you know there were three?</p> <p>25 A. No.</p>

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<p>1 Q. Okay. What two versions did you read?</p> <p>2 A. I read the first and the second</p> <p>3 depositions.</p> <p>4 Q. Okay.</p> <p>5 A. That's the transcript of each one.</p> <p>6 Q. You didn't read the third version?</p> <p>7 A. No.</p> <p>8 Q. So your opinions can't be influenced in</p> <p>9 any way by what she said in her third deposition,</p> <p>10 correct?</p> <p>11 A. No, I have not read it, I cannot rely on</p> <p>12 it.</p> <p>13 Q. And you don't intend to give any opinions</p> <p>14 based on anything that was said in her third</p> <p>15 deposition?</p> <p>16 A. I'm not even aware that there was a third</p> <p>17 deposition, so I definitely could not rely on.</p> <p>18 Q. So anything that was said in the third</p> <p>19 deposition can't form any basis for any opinion you're</p> <p>20 giving, correct?</p> <p>21 A. Unless I read them before trial, and then</p> <p>22 everybody should be aware if anything changes.</p> <p>23 Q. I'm talking about as you sit here today,</p> <p>24 we've got your report, we've got you here under oath</p> <p>25 giving your opinions, you can't opine, don't intend to</p>	<p>1 hospital, and I put together the research, I cooperate</p> <p>2 with the research instruments, I oversee the research</p> <p>3 instruments as the principal investigator. That</p> <p>4 includes IRB submissions and registering in the</p> <p>5 clinicaltrials.gov site.</p> <p>6 Q. But the registry is closed?</p> <p>7 A. Yes, when we finish our project, we are</p> <p>8 required to close that registry or that project on the</p> <p>9 clinicaltrials.gov.</p> <p>10 Q. So you're no longer an investigator for</p> <p>11 that?</p> <p>12 A. No.</p> <p>13 Q. I guess we should take that out of your</p> <p>14 résumé, should we not?</p> <p>15 A. You can actually strike it, yeah.</p> <p>16 Q. Okay. And it says that, the conference</p> <p>17 director for the Pelvic Floor Board. What is that?</p> <p>18 A. The Pelvic Floor Board is a group of</p> <p>19 colorectal, radiologists, physical therapists,</p> <p>20 gastroenterologists, neurologists, urogynecologists,</p> <p>21 gynecologists, and neurologists and pain management</p> <p>22 specialists. We all get together every quarter and we</p> <p>23 present cases, discuss cases and treatment strategies</p> <p>24 and share knowledge.</p> <p>25 Q. Is this national or international, or is</p>
Page 23	Page 25
<p>1 opine on anything said in her third deposition?</p> <p>2 A. No, I have not read it.</p> <p>3 Q. Okay. Now, real quickly, you're the</p> <p>4 medical director of South Miami Medical Arts Surgery,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. And that's, that's where you work?</p> <p>8 A. That's one of the places where I work.</p> <p>9 That's, that's a surgery center that is a partnership</p> <p>10 between the surgeons and Baptist Health System.</p> <p>11 Q. And what do you do as the medical</p> <p>12 director?</p> <p>13 A. I oversee credentialing, oversee the</p> <p>14 directory for pharmacy, I oversee any incidents,</p> <p>15 incident reports, and I, I also prepare for joint</p> <p>16 commission reviews and AHCA, A-H-C-A, reviews.</p> <p>17 Q. It says you are a principal investigator</p> <p>18 of the Fibroid Registry Research Project. What is</p> <p>19 that?</p> <p>20 A. Yes, that's a registry, it's a research,</p> <p>21 and, it's a research project, and it was registered and</p> <p>22 has been closed.</p> <p>23 Q. What was it a research project of? And</p> <p>24 what was the purpose of the project?</p> <p>25 A. Well, there's a fibroid center at the</p>	<p>1 that just here in Miami?</p> <p>2 A. That's a CME activity. It's one-credit</p> <p>3 CME activity here at Baptist Health.</p> <p>4 Q. Okay, that's what I'm getting at, it's a</p> <p>5 local entity?</p> <p>6 A. That's correct.</p> <p>7 Q. And you set up the conferences for it?</p> <p>8 A. Yes, I'm the conference director.</p> <p>9 Q. Okay. Now, you're a member of the</p> <p>10 American Urologic, Urogynecologic Society, is that</p> <p>11 right?</p> <p>12 A. Yes.</p> <p>13 Q. That is an organization made up of</p> <p>14 doctors who practice urology and gynecology?</p> <p>15 A. Yeah, we, AUGS started in the '90s, and</p> <p>16 it was put together by Dr. Jack Robertson, and he, now</p> <p>17 it's just the society that represents those with an</p> <p>18 interest or a board certification in urogynecologic</p> <p>19 medicine and reconstructive surgery.</p> <p>20 Q. That's commonly referred as to AUGS?</p> <p>21 A. AUGS.</p> <p>22 Q. And am I correct, as long as you're a</p> <p>23 doctor practicing urology or urogynecology and you</p> <p>24 submit your application, you can be a member of the</p> <p>25 organization, correct?</p>

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<p>1 A. That's correct.</p> <p>2 Q. You don't have to take a test to get in</p> <p>3 there?</p> <p>4 A. No.</p> <p>5 Q. You don't have to be invited?</p> <p>6 A. No.</p> <p>7 Q. You're just, I'm a doctor, I do</p> <p>8 gynecology, I do urology, I would like to be a member,</p> <p>9 here's my dues, I'm in, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay, and in fact, Ethicon is a member of</p> <p>12 AUGS, is that correct?</p> <p>13 A. I did not know that.</p> <p>14 Q. Is me telling you, is that the first time</p> <p>15 you ever heard it?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And then it says that you're a</p> <p>18 member of the American Urological Association, AUA, is</p> <p>19 that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Same thing, that's an organization that</p> <p>22 you don't have to be invited to, correct?</p> <p>23 A. No, that one I was invited.</p> <p>24 Q. You don't have to be invited to it,</p> <p>25 correct?</p>	<p>1 Urogynecologic Association?</p> <p>2 A. Yes.</p> <p>3 Q. Is that IUGA?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. What about that organization, do</p> <p>6 you have to be invited to that, or can you simply join</p> <p>7 it?</p> <p>8 A. No, you join.</p> <p>9 Q. Okay, you pay your dues, submit your</p> <p>10 application, Dr. Sepulveda, you're a member, correct?</p> <p>11 A. Yes.</p> <p>12 Q. ICS, International Continence Society,</p> <p>13 that's also a group, that was founded in England,</p> <p>14 right?</p> <p>15 A. I don't know if it was founded in</p> <p>16 England. I know it's a great source of information.</p> <p>17 Q. And that's simply, I'm Jaime Sepulveda</p> <p>18 and I want to be a member, here's my money and here's</p> <p>19 my application, and you're in, correct?</p> <p>20 A. Yes.</p> <p>21 Q. All right, you were not invited to be a</p> <p>22 member of ICS?</p> <p>23 A. No.</p> <p>24 Q. Anybody who is a doctor who pays the dues</p> <p>25 can be a member of ICS, correct?</p>
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<p>1 A. For me as a gynecologist to be a member,</p> <p>2 yes.</p> <p>3 Q. Generally, anyone who is a practicing</p> <p>4 urologist who wants to be a member of the AUA can</p> <p>5 submit an application to be a member, correct?</p> <p>6 A. If you are a urologist.</p> <p>7 Q. That's my point. And you are.</p> <p>8 A. No, I'm a urogynecologist.</p> <p>9 Q. I understand, but you practice urology</p> <p>10 and gynecology, do you not?</p> <p>11 A. I practice female pelvic medicine and</p> <p>12 reconstructive surgery. That's my board certification.</p> <p>13 Q. And, so, any doctor who practices in that</p> <p>14 field can apply, pay a due and be a member of AUA,</p> <p>15 correct?</p> <p>16 A. I think for urologists, they are board</p> <p>17 certified in urology. I am not sure.</p> <p>18 Q. As you sit here today, you didn't have to</p> <p>19 take a test to be an AUA member, did you?</p> <p>20 A. No, for me to be a member, I had to be</p> <p>21 invited and sponsored by a urologist.</p> <p>22 Q. And then you pay your dues and you become</p> <p>23 a member, correct?</p> <p>24 A. Yes.</p> <p>25 Q. All right. The IUA, the International</p>	<p>1 A. Yes.</p> <p>2 Q. Does your experience in neuromodulation</p> <p>3 have anything to do with the opinions you're giving in</p> <p>4 this case?</p> <p>5 A. No, not neuromodulation.</p> <p>6 Q. It's in your report, so I just want to</p> <p>7 make sure, as I go through this, I want to see if it</p> <p>8 impacts your opinions, and if it doesn't, we won't</p> <p>9 spend any time on it.</p> <p>10 A. No, neuromodulation is used for urge</p> <p>11 incontinence, but it's not something that I would</p> <p>12 recommend for Mrs. Ramirez at this time.</p> <p>13 Q. And you said that you have a good bit of</p> <p>14 experience with TVT, TVTO and TVT Secur, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you describe it in your report as</p> <p>17 three generations of TVT products, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And all three of those use the</p> <p>20 same mesh, correct?</p> <p>21 A. Yes.</p> <p>22 Q. The, the method of implanting is</p> <p>23 different, correct?</p> <p>24 A. Yes.</p> <p>25 Q. The length is different?</p>

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<p>1 A. Yes.</p> <p>2 Q. And, but in your mind, those three</p> <p>3 products represent three different generations of, of</p> <p>4 the TVT family of products?</p> <p>5 A. Yes.</p> <p>6 Q. All right. You also implant TVT</p> <p>7 Abbrevos, do you not?</p> <p>8 A. Yes.</p> <p>9 Q. Is that part of the third generation, or</p> <p>10 is it a fourth generation, or where do you put Abbrevo</p> <p>11 in the hierarchy of --</p> <p>12 A. It's probably, we're going to call it</p> <p>13 fourth generation just by when they came in.</p> <p>14 Q. Okay. It was put on the market in 2010</p> <p>15 after, after the other three, correct?</p> <p>16 A. It might be around that time.</p> <p>17 Q. I'm just curious why you didn't put</p> <p>18 Abbrevo in your report.</p> <p>19 A. I don't know, probably just going the</p> <p>20 Abbrevo in the same, in my mind I think it's the same</p> <p>21 way as the TVTO.</p> <p>22 Q. It's an obturator approach?</p> <p>23 A. It's a transobturator approach with</p> <p>24 midurethral synthetic sling.</p> <p>25 Q. And you put a lot of Abbrevos in, don't</p>	<p>1 Q. Did you ever look up decommercialization</p> <p>2 in the dictionary?</p> <p>3 A. Never looked at it.</p> <p>4 Q. It doesn't exist, I'll invite you to look</p> <p>5 it up. What you mean by decommercialization is, TVT</p> <p>6 Secur was taken off the market by Ethicon, was it not?</p> <p>7 MS. GALLAGHER: Object to form.</p> <p>8 A. What I consider is that they don't sell</p> <p>9 it anymore.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. That's right, because they don't make it</p> <p>12 anymore and they don't market it anymore, correct?</p> <p>13 A. They don't sell it, they don't market it</p> <p>14 anymore.</p> <p>15 Q. And why don't they market it anymore?</p> <p>16 MS. GALLAGHER: Object to form.</p> <p>17 A. It was a decision that came on, on a</p> <p>18 letter that they explained that, because there were</p> <p>19 other, other -- there was other methodology that was</p> <p>20 going to be used for submission to the FDA. They, they</p> <p>21 could not make it anymore. They decided not to make it</p> <p>22 anymore.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. And they decided not to make it anymore</p> <p>25 because the FDA told them that the FDA was not</p>
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<p>1 you?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. You're not putting the Secur in</p> <p>4 anymore, correct?</p> <p>5 A. I don't have it.</p> <p>6 Q. Okay. Because it was taken off the</p> <p>7 market, wasn't it?</p> <p>8 A. I don't have it, I just don't have it</p> <p>9 available.</p> <p>10 Q. I know you don't, and the reason you</p> <p>11 don't have it is because it's not made anymore, is it?</p> <p>12 A. It's not made anymore.</p> <p>13 Q. Because Ethicon took it off the market,</p> <p>14 correct?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. Yeah, they decommercialized it.</p> <p>17 BY MR. FREESE:</p> <p>18 Q. Well, decommercialization, is that what</p> <p>19 you mean, they decommercialized it?</p> <p>20 A. Yeah, that's the term that has been used.</p> <p>21 Q. That's not even a word, is it?</p> <p>22 A. I don't know.</p> <p>23 Q. I mean, I'm not trying to be funny.</p> <p>24 Decommmercialization is not even a word, is it, Doctor?</p> <p>25 A. I don't know.</p>	<p>1 satisfied with the safety of the TVT Secur, correct?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. I think that it was -- I don't know if it</p> <p>4 was about safety, I think it was more about getting</p> <p>5 post-market surveillance.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. You know that the FDA sent a letter to</p> <p>8 Ethicon saying that it was not satisfied that the</p> <p>9 safety of the TVT Secur was established and therefore</p> <p>10 the company was going to be required to do 522 studies</p> <p>11 in order to keep marketing the product, and rather than</p> <p>12 do the studies to prove the safety, the company took</p> <p>13 the product off the market, correct?</p> <p>14 MS. GALLAGHER: Object to form.</p> <p>15 A. I know that there was a request for a</p> <p>16 522. I cannot tell you that it was because of safety.</p> <p>17 BY MR. FREESE:</p> <p>18 Q. Well, what else does the FDA regulate</p> <p>19 products for other than safety?</p> <p>20 A. They, they, they do safety, efficacy and</p> <p>21 quality of products.</p> <p>22 Q. Okay, and as you sit here today, do you</p> <p>23 know of anybody disputing the quality of the TVT Secur?</p> <p>24 A. No.</p> <p>25 Q. Do you know of anybody disputing the</p>

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<p>1 efficacy of the TVT Secur?</p> <p>2 A. No.</p> <p>3 Q. You do know that they were disputing the</p> <p>4 safety of the TVT Secur, correct?</p> <p>5 A. I do not know that.</p> <p>6 Q. As you sit here today, you have no idea</p> <p>7 why the company took the TVT Secur off the market?</p> <p>8 A. I, I don't have a clear idea why.</p> <p>9 Q. And does the 522 order relate to the</p> <p>10 safety of a product or the efficacy of a product?</p> <p>11 A. I think it has to do with post-market</p> <p>12 surveillance.</p> <p>13 Q. And is post-market surveillance focused</p> <p>14 on safety or efficacy?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I already say I don't know if it's about</p> <p>17 safety. I know a post-market surveillance is a lot</p> <p>18 more involved than just safety.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. You think post-market surveillance has to</p> <p>21 do with the efficacy of a product?</p> <p>22 A. I believe it does.</p> <p>23 Q. And you think the criticism that the FDA</p> <p>24 had in the post-market surveillance of TVT Secur was</p> <p>25 because of the efficacy of the product?</p>	<p>1 Q. All right. Look at page 4, if you don't</p> <p>2 mind, sir.</p> <p>3 MS. GALLAGHER: What document are you</p> <p>4 looking at?</p> <p>5 MR. FREESE: I'm looking at this</p> <p>6 document.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. Is that the same one you're looking at?</p> <p>9 A. Yes, this is the FDA Executive Summary</p> <p>10 for surgical mesh for treatment of women with pelvic</p> <p>11 organ prolapse and stress urinary incontinence.</p> <p>12 Q. Look at page 4, section 2.3, regarding</p> <p>13 522 post-market surveillance studies.</p> <p>14 A. I'm looking at page 4.</p> <p>15 Q. Okay. Is this what you needed to look at</p> <p>16 to answer the question?</p> <p>17 A. No, I was looking at the decision of the</p> <p>18 committee on the post-market option. Yes. What would</p> <p>19 you like me to read?</p> <p>20 Q. My question is, the post-market</p> <p>21 surveillance studies that the FDA had required Ethicon</p> <p>22 to conduct related to the serious adverse health</p> <p>23 consequences that may be caused by a failure of the</p> <p>24 product, correct?</p> <p>25 A. About the, about the efficacy and safety</p>
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<p>1 MS. GALLAGHER: Object to the form.</p> <p>2 A. There was a, there was a, now that you</p> <p>3 mentioned it -- can I refer to one of my documents?</p> <p>4 Because it's in my, it's in one of the documents that I</p> <p>5 brought.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Sure. Do you need to look at a document</p> <p>8 to answer my question?</p> <p>9 A. Well, we have been talking about the same</p> <p>10 question already in four separate instances, and if I'm</p> <p>11 going to answer your question accurately I would like</p> <p>12 to refer to my document.</p> <p>13 Q. You mean four separate depositions you've</p> <p>14 given?</p> <p>15 A. I don't understand your question.</p> <p>16 Q. I don't understand your answer. You said</p> <p>17 we've been talking about it in four separate instances.</p> <p>18 What did you mean, sir?</p> <p>19 A. Well, you asked me already about safety</p> <p>20 and that the 522 has to do with safety, and before I</p> <p>21 give you an answer I want to make sure that I give you</p> <p>22 an accurate answer, and I want to see the document.</p> <p>23 Q. Go ahead.</p> <p>24 A. I'm looking at the white paper from the</p> <p>25 FDA.</p>	<p>1 and quality.</p> <p>2 Q. About the, the 522 allows the FDA to</p> <p>3 order the study where the failure of the device was</p> <p>4 reasonably likely to have a serious adverse health</p> <p>5 consequence. Correct?</p> <p>6 A. Are you reading on the pelvic organ</p> <p>7 prolapse section?</p> <p>8 Q. I'm reading page 4 on 522 studies.</p> <p>9 A. Yes. Well, I'm going to read on page 47,</p> <p>10 which is a more specific question about TVT Secur.</p> <p>11 Q. Okay. Go ahead.</p> <p>12 A. The panel will be asked to consider</p> <p>13 whether 522 studies are needed for cleared mini-slugs,</p> <p>14 all cleared surgical mesh indicated for stress urinary</p> <p>15 incontinence, not needed for these devices. If the</p> <p>16 panel believes 522 are needed for all or just a subset</p> <p>17 of these products, the panel will be asked to discuss</p> <p>18 the type clinical study that should be required with</p> <p>19 consideration to patient selection, controls,</p> <p>20 randomizations, outcome measures, concomitant</p> <p>21 surgeries, follow-up duration, etcetera.</p> <p>22 Q. Okay, and you agree with the FDA</p> <p>23 statements in the summary about the TVT Secur?</p> <p>24 A. I, I agree that they are in all the power</p> <p>25 to choose whatever method they decide to choose.</p>

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<p>1 Q. I understand, but do you agree with the</p> <p>2 comments that they made about the safety of the TVT</p> <p>3 Secur?</p> <p>4 A. I don't think that TVT Secur is an unsafe</p> <p>5 procedure; therefore, I see no reason to go beyond what</p> <p>6 was already being done. Now, I do understand that will</p> <p>7 benefit from surveillance in any product in which there</p> <p>8 are being reports of any, any type of incident.</p> <p>9 Q. Rather than do the post-market 522</p> <p>10 studies, the company, rather than approve the safety of</p> <p>11 the product through those post-market studies, chose to</p> <p>12 take it off the market, correct?</p> <p>13 MS. GALLAGHER: Object to form.</p> <p>14 A. The safety of the product has been, is</p> <p>15 already being examined independently from the FDA.</p> <p>16 There have been through, there have been studies</p> <p>17 through separate, separate studies and trials. What</p> <p>18 they, the FDA decided was to do 522 because that's a</p> <p>19 mechanism that they have in place.</p> <p>20 BY MR. FREESE:</p> <p>21 Q. All you're saying is the FDA did what</p> <p>22 they have the right to do. I'm asking you if you</p> <p>23 agreed with what they did.</p> <p>24 MS. GALLAGHER: Object to form.</p> <p>25 A. I, I disagree with the methodology of the</p>	<p>1 A. That's correct. I think it's based on</p> <p>2 the best science that they consider, but there's a bias</p> <p>3 on the methodology to come to their conclusions and</p> <p>4 recommendations.</p> <p>5 Q. Can you describe to me, Dr. Sepulveda,</p> <p>6 what bias the FDA has?</p> <p>7 A. Well, it's a very small group, and, and</p> <p>8 it's, it's a group, I believe it's 12, 12 individuals,</p> <p>9 and the methodology used on the statistical analysis</p> <p>10 was not, was not fully, fully completed, fully</p> <p>11 disclosed, I should have said, fully disclosed. Also,</p> <p>12 the way the complaint were examined, from the MAUDE,</p> <p>13 from the MAUDE database was put through an Excel</p> <p>14 program, it was required to be placed on an Excel</p> <p>15 program to trim down the repeated complaints. So, the</p> <p>16 MAUDE database was used but there's, within itself has</p> <p>17 its own, its own limitations.</p> <p>18 I'm going to, I'm going to, I'm going to</p> <p>19 read the limitations of the MAUDE data analysis, which</p> <p>20 is on the FDA reports, in which it says the reports</p> <p>21 were unduplicated using Excel on duplication function,</p> <p>22 not by reviewing the individual reports. A few</p> <p>23 unduplicated reports might still exist in the data.</p> <p>24 This auto function does not exemplify reports that have</p> <p>25 different numbers but are related to the same events.</p>
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<p>1 FDA which has proven to this time to be inadequate to</p> <p>2 regulate and innovate at the same time. This type of</p> <p>3 criminology of 522s or 510(k)s have been in place for a</p> <p>4 long period of time, and it's, there's a consensus that</p> <p>5 this need to be reviewed. Now, at the time that this</p> <p>6 was decided, all this consensus came through, the 522</p> <p>7 was the mechanism in place.</p> <p>8 BY MR. FREESE:</p> <p>9 Q. Right. You read the executive summary,</p> <p>10 did you not?</p> <p>11 A. I did.</p> <p>12 Q. And you read it in forming your opinions</p> <p>13 in this case?</p> <p>14 A. Yes.</p> <p>15 Q. And you agree with all the, the FDA</p> <p>16 statements in the summary?</p> <p>17 A. No, I don't agree with all of them and I</p> <p>18 don't disagree with all of them.</p> <p>19 Q. You disagree with some and agree with</p> <p>20 others?</p> <p>21 A. There are parts in which I have no</p> <p>22 opinion.</p> <p>23 Q. I guess it would be fair to say you don't</p> <p>24 think that FDA statements are always well founded in</p> <p>25 science, correct?</p>	<p>1 If one event has two reports, one from the manufacturer</p> <p>2 and one from voluntary reporter, but they are not</p> <p>3 linked in the MAUDE database as one event, they will</p> <p>4 not be taped by auto function as one event.</p> <p>5 So, that tells you the accuracy of the</p> <p>6 data that was obtained on, on, on this recommendations.</p> <p>7 In addition, even though the result of</p> <p>8 data mining were refined multiple times, it is still</p> <p>9 possible that a few reports are placed in the wrong</p> <p>10 group and in the wrong adverse event group.</p> <p>11 I just read the way, the way the FDA</p> <p>12 itself, the group, says that there's a limitation about</p> <p>13 data analysis. That is biased.</p> <p>14 Q. And, therefore, you think that</p> <p>15 conclusions that the FDA reached are unreliable?</p> <p>16 A. I think that they were biased.</p> <p>17 Q. Okay, and therefore, if they're biased,</p> <p>18 they're unreliable, correct?</p> <p>19 A. They're not accurate.</p> <p>20 Q. And if they're not accurate, they're not</p> <p>21 reliable?</p> <p>22 A. If you want to equate accurate with</p> <p>23 reliable, yes.</p> <p>24 Q. I just want to see if you agree with me.</p> <p>25 A. Well, reliable is more, is no more the</p>

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<p>1 word of accuracy. Reliable is how good the</p> <p>2 methodology and conclusions are.</p> <p>3 Q. And if methodology is biased, that would</p> <p>4 lead to unreliable results, correct?</p> <p>5 A. I think that most people would judge it</p> <p>6 as unreliable.</p> <p>7 Q. I mean, you understand evidence-based</p> <p>8 medicine, correct?</p> <p>9 A. Yes.</p> <p>10 Q. If you're practicing evidence-based</p> <p>11 medicine, you don't want unreliable data to rely on, do</p> <p>12 you?</p> <p>13 A. No, I want the most accurate data that I</p> <p>14 can obtain.</p> <p>15 Q. And, therefore, bias would be a type of</p> <p>16 unreliable data, correct?</p> <p>17 MS. GALLAGHER: Object to form.</p> <p>18 A. There's no cohort methodology, there's no</p> <p>19 randomization, there's no actual analysis conducted on</p> <p>20 this. The whole, the whole concept of evaluating</p> <p>21 either efficacy or quality in general, in general, I'm</p> <p>22 talking in general now, in general, we already</p> <p>23 mentioned for mini-slings and now we're talking in</p> <p>24 general, in general is that the amount of database is</p> <p>25 not accurate, and if it's not accurate, you cannot</p>	<p>1 you have had over 500 surgeons visit your operating</p> <p>2 room to watch you place slings, correct?</p> <p>3 A. Yes.</p> <p>4 Q. How many of those were sponsored by</p> <p>5 Ethicon?</p> <p>6 A. I think that the majority of them.</p> <p>7 Q. Well, I mean, like 99 percent or 51</p> <p>8 percent?</p> <p>9 A. I never run a percentage of it, but I</p> <p>10 have had, I have had surgeons that come without,</p> <p>11 without Ethicon. The majority could be more than 50</p> <p>12 percent. This, this pelvic floor, pelvic floor surgery</p> <p>13 and the specific procedures did not start with mesh.</p> <p>14 We were doing this procedures and we were using</p> <p>15 different procedures even before mesh. In the same way</p> <p>16 that I visited many surgeons, even before there was</p> <p>17 mesh, they also visited me.</p> <p>18 Q. Okay. Well, did you place any</p> <p>19 midurethral slings that weren't synthetic?</p> <p>20 Midurethral slings by definition are synthetic slings,</p> <p>21 are they not?</p> <p>22 A. Yes, there's no data that indicates that</p> <p>23 midurethral slings should be anything but synthetic.</p> <p>24 Q. I understand. My question, Doctor, I'm</p> <p>25 asking you about your report, and you said 500 doctors</p>
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<p>1 consider reliable.</p> <p>2 BY MR. FREESE:</p> <p>3 Q. Thank you. And, Dr. Sepulveda, do you</p> <p>4 think that you are more qualified to assess the safety</p> <p>5 and efficacy of mesh products than the FDA?</p> <p>6 A. I, I cannot substitute a panel of 12</p> <p>7 people. I cannot substitute a cohort study. It's not</p> <p>8 that I'm more qualified. I, I am the receiving end of</p> <p>9 it. So, I can tell you in this receiving end how I can</p> <p>10 use it.</p> <p>11 Q. Okay, that's not really my question. My</p> <p>12 question is, do you think that you're more qualified to</p> <p>13 assess the safety and efficacy of mesh products than</p> <p>14 the FDA, yes or no?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I have, I have the experience with</p> <p>17 working with mesh, I have the knowledge on the</p> <p>18 biomechanics of mesh, I have the knowledge on the</p> <p>19 conditions that require the mesh, and I have 25 years</p> <p>20 doing surgery, but that still leaves me in the</p> <p>21 receiving end of it. Am I more qualified than the FDA?</p> <p>22 I think I am as qualified as anyone that was in that</p> <p>23 panel or that spoke to the FDA.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. Now, Doctor, you said in your report that</p>	<p>1 have come to my operating room to watch Dr. Sepulveda</p> <p>2 put in midurethral slings. You did say that, did you</p> <p>3 not?</p> <p>4 A. No, not just midurethral slings.</p> <p>5 Q. Well, let's look at your report, sir.</p> <p>6 Page 2, quote, "I have had over 500 physicians visit my</p> <p>7 operating room to watch me place midurethral slings."</p> <p>8 Did you write that?</p> <p>9 A. Midurethral slings along with other</p> <p>10 procedures.</p> <p>11 Q. That's not what your report says, is it,</p> <p>12 Doctor? Is it?</p> <p>13 A. No, it's not what my report says.</p> <p>14 Q. What your report says is 500 doctors have</p> <p>15 come to your OR to watch you place midurethral slings,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. That means 100 percent of those 500</p> <p>19 doctors would be watching you place a synthetic</p> <p>20 midurethral sling, correct?</p> <p>21 A. Yes, they have watched me place a</p> <p>22 midurethral sling, correct.</p> <p>23 Q. Okay. How many of these 500 doctors that</p> <p>24 came to watch you put synthetic slings in were</p> <p>25 sponsored by Ethicon?</p>

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<p>1 A. The majority.</p> <p>2 Q. Is it closer to 500 or is it closer to</p> <p>3 250?</p> <p>4 A. It might be a number between the both of</p> <p>5 them, but I can not give you an accurate number because</p> <p>6 I never recorded it.</p> <p>7 Q. Okay. How do you know it's 500 then, if</p> <p>8 you never recorded it?</p> <p>9 A. Because that's the number, that's the</p> <p>10 number that -- it may have been a thousand.</p> <p>11 Q. Okay.</p> <p>12 A. It may have been a thousand, may have</p> <p>13 been 400, but I can tell you that at least 500, because</p> <p>14 in 25 years doing surgery and you have individuals</p> <p>15 coming to watch you.</p> <p>16 Q. Did you just pick the 500 out of the air?</p> <p>17 A. Yeah, that's the safest number I could</p> <p>18 pick. I could have picked a larger number, though.</p> <p>19 Q. Okay. And how many years have you been</p> <p>20 doing midurethral slings?</p> <p>21 A. It's since TVT came out.</p> <p>22 Q. 1998?</p> <p>23 A. Yes.</p> <p>24 Q. All this 25-year stuff you're talking</p> <p>25 about has nothing to do with when you're talking about</p>	<p>1 that come and watch me place it. That's essentially.</p> <p>2 I could go on with a list, but I don't keep a registry.</p> <p>3 Q. All right. And when, when Ethicon</p> <p>4 sponsors these doctors to come watch you place slings,</p> <p>5 is Ethicon paying you to do that?</p> <p>6 A. Yes, they, they, they were, those were</p> <p>7 mostly activities in which I demonstrated how to place</p> <p>8 product, and some patients with product also had a</p> <p>9 midurethral sling.</p> <p>10 Q. Okay, but when these doctors that are</p> <p>11 sponsored by Ethicon are coming in, you're being paid</p> <p>12 by Ethicon to let them come into your OR to watch you</p> <p>13 do surgeries?</p> <p>14 A. Yeah, they compensate me for my time</p> <p>15 before I do my surgery. When I'm doing my surgery, I'm</p> <p>16 being compensated for my surgery.</p> <p>17 Q. Now, you say that you, you've used</p> <p>18 laser-cut mesh and mechanically-cut mesh, correct?</p> <p>19 A. Yes.</p> <p>20 Q. If I'm holding a TVTO box, for example,</p> <p>21 all right, how can I tell if it's a mesh, if the mesh</p> <p>22 is laser cut or mechanically cut?</p> <p>23 A. I don't know by looking at the box</p> <p>24 because when I'm scrubbed, I'm not looking at a box but</p> <p>25 I look at the product.</p>
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<p>1 midurethral slings, does it?</p> <p>2 A. No, we, we actually dissected the</p> <p>3 urethra, so that -- okay, yes --</p> <p>4 Q. Just answer my question, Doctor. All of</p> <p>5 this talk about I've been doing this 25 years has no</p> <p>6 application to midurethral slings, does it?</p> <p>7 A. Yes, I have not placed midurethral slings</p> <p>8 for 25 years.</p> <p>9 Q. Because they've only been on the market</p> <p>10 for 18 years, correct?</p> <p>11 A. That is correct.</p> <p>12 Q. Okay, and no 500 doctors have seen you</p> <p>13 place a midurethral sling?</p> <p>14 A. It might be 500, it might be more.</p> <p>15 Q. And who comes and sees you place</p> <p>16 midurethral slings in the OR other than people</p> <p>17 sponsored by Ethicon?</p> <p>18 A. I have, I have colleagues that come in, I</p> <p>19 do Miami, they come to Miami, and they say I'm going to</p> <p>20 go and see Jaime do surgery. The first one that comes</p> <p>21 to mind is the chairman, the director of gynecologic</p> <p>22 surgery at the University of Puerto Rico. Another</p> <p>23 colleague in Savannah. Another colleagues also from</p> <p>24 Puerto Rico that is doing academics. I have had</p> <p>25 fellows, I have had residents from other institutions</p>	<p>1 Q. Okay. So, you're an expert, you hold</p> <p>2 yourself out as an expert in TVTO, correct?</p> <p>3 A. Right.</p> <p>4 Q. And we can agree that if you're looking</p> <p>5 at the box, even you, who implants them all the time,</p> <p>6 you don't know if it's mechanical cut or laser cut?</p> <p>7 A. I think that there's a way to know it. I</p> <p>8 just never looked at that box.</p> <p>9 Q. But sitting here today, you can't think</p> <p>10 of what that way is?</p> <p>11 A. Yeah, I look at the sling.</p> <p>12 Q. Okay, you pull it out and you look at it,</p> <p>13 so you don't know until you open the box, pull back</p> <p>14 the, the plastic cover to figure out if it's laser cut</p> <p>15 or mechanical cut?</p> <p>16 A. No, not with the plastic cover. You can</p> <p>17 actually see it on the sheet.</p> <p>18 Q. But you have to open the plastic</p> <p>19 container to get to the TVTO, do you not?</p> <p>20 A. No, it's transparent. You can actually</p> <p>21 see it without even opening it.</p> <p>22 Q. Well, the body is transparent, the top is</p> <p>23 not transparent, is it?</p> <p>24 A. The body, yeah, all the other sides are</p> <p>25 transparent.</p>

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<p>1 Q. The tub is transparent but the top is 2 not?</p> <p>3 A. No, the top is like a paper with a name.</p> <p>4 Q. And you can look through the plastic tub 5 and tell if it's laser cut or mechanical cut?</p> <p>6 A. You can look at the sling in that area, 7 yes.</p> <p>8 Q. Without opening it?</p> <p>9 A. Without opening it.</p> <p>10 MS. GALLAGHER: Y'all are talking about 11 different things. He's talking about the top 12 of the box. Can you look through the top of 13 the box and tell whether it's laser cut or 14 machine cut?</p> <p>15 THE WITNESS: No.</p> <p>16 MR. FREESE: I understand what he was 17 saying.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. You're saying you can look through the 20 clear plastic portion of the TVT before you even open 21 the tub and tell if it's laser cut or mechanical cut?</p> <p>22 A. I have used it so many times and I have, 23 and there's a plastic cover in there, and you can see 24 the whole device right through there. It's, it's, if I 25 tell you, though, in order to be accurate with you, I</p>	<p>1 A. No, I have ordered just, just give me 2 five TVTOs. Actually, you know, I don't tell someone I 3 need TVTOs. Someone keeps my TVTOs there and, and, and 4 I don't, I don't order like I would say that I order 5 things for my office, no.</p> <p>6 Q. Okay, but what I'm getting at is, when 7 you, I mean, you are the doctor and if a TVTO is needed 8 to be implanted in your patient, do you know whether or 9 not it's a laser cut or mechanical cut?</p> <p>10 A. Well, I look at it.</p> <p>11 Q. At the time of the placement?</p> <p>12 A. At the time that I have it there.</p> <p>13 Q. Yes, sir, what I'm trying to find out is 14 at the time that you buy it from Ethicon, are you 15 dictating it be one or the other?</p> <p>16 A. No.</p> <p>17 Q. Who does that?</p> <p>18 A. They, they, they order it from, from the 19 company. There's no one that determines laser cut or 20 mechanical cut.</p> <p>21 Q. And it doesn't make any difference to you 22 which one it is?</p> <p>23 A. No.</p> <p>24 Q. Am I correct that after the TVTO laser 25 cut was introduced, Ethicon introduced several more</p>
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<p>1 cannot tell you that I look right through there and 2 say, okay, which one is that, laser cut or mechanical 3 cut.</p> <p>4 Q. I'm asking you, are you able to do that?</p> <p>5 A. I will have to look at it, because as I 6 sit here today, I don't remember looking through it.</p> <p>7 Q. When you open it and pull it out, it's 8 got a plastic sheath on it, does it not?</p> <p>9 A. It does.</p> <p>10 Q. Well, can you see the edges?</p> <p>11 A. Yes.</p> <p>12 Q. And you can tell if it's laser cut or 13 mechanical cut without ever pulling the plastic sheath 14 back?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Is there any study that you have 17 looked at that compared how laser-cut versus 18 mechanical-cut mesh performs?</p> <p>19 A. No.</p> <p>20 Q. Do you order the slings, Doctor, that you 21 implant in your patients?</p> <p>22 A. No, the hospital orders it.</p> <p>23 Q. When, when you order them, do you tell 24 the hospital I need five TVTOs, or do you say, I need 25 five TVTO laser cut or five TVTO mechanical cut?</p>	<p>1 synthetic sling products, correct?</p> <p>2 A. I overheard on the, on the different 3 conferences and activities by Ethicon that there was, 4 they were talking about laser cut and mechanical cut. 5 It never made a difference to me, laser cut or 6 mechanical cut.</p> <p>7 Q. And is that -- it's fair to say then that 8 you've actually never studied the clinical differences 9 between laser cut and mechanical cut?</p> <p>10 A. No, there has been no actual clinical 11 studies to my knowledge, and if you have something that 12 I don't know, please, I will read it.</p> <p>13 Q. Sure, and that's fine, Doctor, but my 14 question to you is, and I think you may have told me, 15 there are no studies comparing laser cut to mechanical 16 cut and you have not endeavored in forming your 17 opinions in this case to do any studies on the 18 difference from a clinical standpoint of laser cut 19 versus mechanical cut, correct?</p> <p>20 A. To my knowledge, there has not been a 21 randomized control trial comparing laser cut versus 22 mechanical cut.</p> <p>23 Q. Yes, sir, I understand that, and nor have 24 you done any kind of literature search to see if 25 there's any literature, even if it's not a randomized</p>

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<p>1 control trial, correct, about the difference between</p> <p>2 mechanical cut versus laser cut?</p> <p>3 A. No, there's no -- I actually look for</p> <p>4 mechanical cut versus laser cut, and what I have is</p> <p>5 what's in the company documents.</p> <p>6 Q. So the only documents you've looked at</p> <p>7 that discuss the difference between mechanical cut and</p> <p>8 laser cut is what the company lawyers supplied you?</p> <p>9 A. Yes, the company documents.</p> <p>10 Q. And you've done no other independent</p> <p>11 literature review or scientific review of any</p> <p>12 literature on any difference that may exist between</p> <p>13 laser cut and mechanical cut from a clinical</p> <p>14 standpoint?</p> <p>15 A. I did an PubMed search and I could not</p> <p>16 find any.</p> <p>17 Q. Okay. The only documents that you have</p> <p>18 looked at comparing laser cut to mechanical cut are the</p> <p>19 internal documents of Ethicon, correct?</p> <p>20 A. That is correct.</p> <p>21 MR. FREESE: Let's take a break.</p> <p>22 (Break taken from 10:25 to 10:30 a.m.)</p> <p>23 BY MR. FREESE:</p> <p>24 Q. Dr. Sepulveda, before our break we were</p> <p>25 talking about laser cut versus mechanical cut, and real</p>	<p>1 midurethral sling that Ethicon manufactured after the</p> <p>2 introduction of TVTO that was anything other than</p> <p>3 laser-cut mesh, correct?</p> <p>4 A. I cannot think of any other.</p> <p>5 Q. And do you have any explanation why that</p> <p>6 was, why they don't make mechanically-cut mesh in any</p> <p>7 of the products once laser-cut TVTO became available?</p> <p>8 MS. GALLAGHER: Object to form.</p> <p>9 A. I did not know the reason for it.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. Okay. Doctor, in your overview and</p> <p>12 review of literature, you say stress urinary</p> <p>13 incontinence is a common condition in women, and we can</p> <p>14 look at some data, but am I correct that, that AUA said</p> <p>15 that up to 50 percent of women will suffer some form of</p> <p>16 the SUI in their lifetime?</p> <p>17 A. I read that, yes.</p> <p>18 Q. And you agree with that?</p> <p>19 A. I would agree with that.</p> <p>20 Q. It's that common of a problem?</p> <p>21 A. It is a very common problem, yes.</p> <p>22 Q. You say all procedures, but in</p> <p>23 particular, you say earlier procedures, in other words</p> <p>24 pre, pre-midurethral sling procedures I gather is what</p> <p>25 you're talking about here?</p>
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<p>1 quickly, I am correct that after TVTO laser cut was</p> <p>2 introduced, Ethicon introduced TVT Secur, correct?</p> <p>3 A. Yes.</p> <p>4 Q. TVT Abbrevio, correct?</p> <p>5 A. Yes.</p> <p>6 Q. TVT Exact, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Am I also correct that after TVTO laser</p> <p>9 cut was introduced, Ethicon never introduced another</p> <p>10 mechanically-cut synthetic midurethral sling again, am</p> <p>11 I correct?</p> <p>12 A. I, I could not track, but I take it as</p> <p>13 you're telling me.</p> <p>14 Q. You agree with me that TVT Secur is laser</p> <p>15 cut, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Every version of it?</p> <p>18 A. Yes.</p> <p>19 Q. TVT Exact is laser cut, is it not, every</p> <p>20 version of it?</p> <p>21 A. Yes.</p> <p>22 Q. TVT Abbrevio is laser cut, every version</p> <p>23 of it, correct?</p> <p>24 A. Yes.</p> <p>25 Q. So you cannot think of a single</p>	<p>1 A. Yes.</p> <p>2 Q. Carry the risk of urinary outlet</p> <p>3 obstruction, voiding dysfunction, major nerve and</p> <p>4 vascular injuries, pain, relatively high frequency of</p> <p>5 revision and wound healing complications?</p> <p>6 A. Yes.</p> <p>7 Q. No previous surgery prior to midurethral</p> <p>8 slings caused a risk of erosion, am I correct?</p> <p>9 A. No, there was exposure of the sutures, we</p> <p>10 did see that, and we did see sutures inside the</p> <p>11 bladder.</p> <p>12 Q. Okay. That's not my question. My</p> <p>13 question is that erosion of the midurethral sling is a,</p> <p>14 is a, is a complication unique to midurethral slings,</p> <p>15 synthetic midurethral slings, correct?</p> <p>16 A. Yes, exposure of the tape was not seen</p> <p>17 before when tapes were not being used.</p> <p>18 Q. Okay, and, Doctor, you say that Burch</p> <p>19 colposuspensions had earlier been associated with the</p> <p>20 term gold standard which established a clinical</p> <p>21 benchmark of efficacy for the treatment of SUI. You</p> <p>22 see that?</p> <p>23 A. Yes.</p> <p>24 Q. I'm read some of your prior depositions,</p> <p>25 so I'm going to try to speed through some of this.</p>

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<p>1 You're not a fan of the phrase gold standard, are you?</p> <p>2 A. Never been much of a fan of that.</p> <p>3 Q. So you're not going to come into court</p> <p>4 and start giving us opinions that the TVTO is the gold</p> <p>5 standard of anything, correct?</p> <p>6 A. I would refer to anything that was</p> <p>7 referred before as a gold standard as the current</p> <p>8 clinical standard.</p> <p>9 Q. Current standard, and in fact, there have</p> <p>10 been articles published in the New England Journal of</p> <p>11 Medicine that say you shouldn't use the word gold</p> <p>12 standard, you should use the word current standard,</p> <p>13 correct?</p> <p>14 A. Yes, it was in -- I don't know if it was</p> <p>15 in the New England Journal of Medicine, but it was</p> <p>16 definitely in the AUGS Journal.</p> <p>17 Q. Okay. And you agree that that's a more</p> <p>18 appropriate phrase to use?</p> <p>19 A. Current clinical standard seems to be a</p> <p>20 more objective way of looking at things.</p> <p>21 Q. And, so, when you come to San Antonio to</p> <p>22 testify, is it fair to say that you're not going to be</p> <p>23 sitting there pontificating about gold standards,</p> <p>24 that's just not a term that you think is appropriate?</p> <p>25 A. I agree, I would not be pontificating</p>	<p>1 trial.</p> <p>2 Q. All right, and the reason I asked you</p> <p>3 about gold standard is because about three pages later</p> <p>4 you then invoke the gold standard language on the TVT.</p> <p>5 A. I actually saw that on my report, and I,</p> <p>6 I apologize for that. That should be current clinical</p> <p>7 standards.</p> <p>8 Q. Okay, and that's fine, and fair enough.</p> <p>9 So, even though you have it in your report, you won't</p> <p>10 be referring to the TVTO as the gold standard?</p> <p>11 A. I'm going to repeat my answer, I will not</p> <p>12 be pontificating about gold standard. I will be saying</p> <p>13 current clinical standards.</p> <p>14 Q. Thank you, sir. You have no idea how</p> <p>15 much time that saved us.</p> <p>16 Doctor, when you say, quote, "The use of</p> <p>17 monofilament, non-absorbable polypropylene predominates</p> <p>18 in the current clinical practice," you're not</p> <p>19 distinguishing between mechanical cut and laser cut?</p> <p>20 A. I'm not distinguishing between one or the</p> <p>21 other.</p> <p>22 Q. Am I correct that in that sentence there,</p> <p>23 when you say that those monofilament non-absorbables</p> <p>24 predominate the current clinical practice, you're</p> <p>25 lumping mechanical cut and laser cut meshes together?</p>
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<p>1 about the gold standard.</p> <p>2 Q. Okay, thank you. Doctor, you said that</p> <p>3 the studies in the medical literature prior to the</p> <p>4 midurethral sling, prior to the arrival of TVT were</p> <p>5 lacking and of poor quality. Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And I'm just, I'm just trying to figure</p> <p>8 out, what is your basis for saying that the studies</p> <p>9 prior to TVT were of poor quality?</p> <p>10 A. Well, there were, there were</p> <p>11 retrospective cohort studies that were case reports,</p> <p>12 there were groups of case reports, but there was a lack</p> <p>13 of randomized control trials.</p> <p>14 Q. Is this just simply, and -- strike that.</p> <p>15 The lack of a substantial number of</p> <p>16 randomized control studies is, is how you reached the</p> <p>17 conclusion that the study quality is poor?</p> <p>18 A. Right.</p> <p>19 Q. In other words, you have to have a</p> <p>20 significant number of randomized control studies in</p> <p>21 order to have good-quality data, in your mind?</p> <p>22 A. I, I look at the, at the cohort studies</p> <p>23 and there are instances in which I may not have a</p> <p>24 randomized control trial. I would like to see multiple</p> <p>25 cohort studies if I don't have a randomized control</p>	<p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. As they are available, because we don't</p> <p>4 have it available anymore in the mechanical cut.</p> <p>5 Q. When did Ethicon stop making TVTO</p> <p>6 mechanical cut?</p> <p>7 A. I, I, I cannot recall one specific date,</p> <p>8 no.</p> <p>9 Q. So, let me clarify that. So, as of</p> <p>10 today, you think all TVTOs are laser cut?</p> <p>11 MS. GALLAGHER: Object to form.</p> <p>12 A. Yes.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. And you don't know exactly when Ethicon</p> <p>15 stopped manufacturing TVTO mechanical-cut mesh?</p> <p>16 MS. GALLAGHER: Object to form.</p> <p>17 A. I don't know a specific date.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. And is that why you said you don't</p> <p>20 concern yourself with it, because it's only laser cut,</p> <p>21 right?</p> <p>22 A. It's only laser cut now.</p> <p>23 Q. All right, thank you. Doctor, you say</p> <p>24 that, quote, "These anatomical considerations," and I'm</p> <p>25 on page 8 of your report if you want to follow along</p>

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<p>1 with me. Quote, "These anatomical considerations were 2 well documented during the description and the design 3 of the TVTO." Do you see that? 4 A. Okay, yes. These anatomical 5 considerations were well documented during the 6 description and design of the TVTO. I am talking about 7 the hammock of the, in the suburethra and the 8 periurethral tissue. 9 Q. All right, and we can agree that prior to 10 the launch of the TVTO, there were no randomized 11 controlled studies of that product done, correct? 12 A. No. 13 Q. Okay, and the product was launched in the 14 U.S. and worldwide without a single randomized control 15 study being performed by Ethicon, correct? 16 A. It was, it was released on a 510(k) 17 approval. 18 Q. And, so, the answer to my question is, at 19 the time the TVTO was released to the world by Ethicon, 20 there were no randomized control studies demonstrating 21 the safety or efficacy of the product, correct? 22 A. That's correct. 23 Q. And the prelaunch studies that Dr. de 24 Laval performed didn't even use the same kit that 25 became the TVTO, did it?</p>	<p>1 A. He's the inventor. 2 Q. And you know he had an economic stake in 3 the results that he reported on his clinical data, 4 correct? 5 A. Yeah, you know, I was asked the same 6 question last week, and these are high-caliber 7 investigators. I have no reason to believe that they 8 are going to be biased specifically by money. I cannot 9 say, I cannot sit here and testify under oath that I 10 believe that that's the case. 11 Q. Okay. Well, I'm simply asking you, you 12 recognize that the only clinical data that existed was 13 that produced by the guy who had an economic stake in 14 the outcome of these results, correct? 15 A. That's correct. 16 Q. Okay. And that data was based on his own 17 pre-cut invention, not what ultimately became TVTO, 18 correct? 19 A. His own device. 20 Q. In other words, de LaVal was using a 21 homemade product when he was implanting women with the, 22 the, his obturator-approach midurethral sling, correct. 23 MS. GALLAGHER: Object to form. 24 A. I don't think he made it at home. He may 25 have made it elsewhere, but I --</p>
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<p>1 A. I think that the needles were, were 2 different. 3 Q. Okay. And he was, he was, he was cutting 4 it himself, correct? 5 A. He may have cut it himself, I'm not aware 6 of which methodology he used for that. 7 Q. Because there was no kit for him to 8 implant in women, he created it, correct? 9 A. He created it. 10 Q. And just so we're clear, Doctor, my 11 question may have lent us to RCTs. At the time that 12 the TVTO was launched by Ethicon, there were no 13 clinical studies whatsoever on the TVTO, correct? 14 A. There were, there were the studies from 15 the, from the inventor, and there was data on the TVT. 16 Q. And I'm not talking about TVT now, 17 because that's a different product, isn't it? 18 A. That, that is, there's a different site 19 on the anatomy where it's inserted. 20 Q. And it's implanted differently, correct? 21 A. It is implanted different. 22 Q. You say there existed the de LaVal 23 clinical data, correct? 24 A. Yes. 25 Q. But he's the inventor, correct?</p>	<p>1 BY MR. FREESE: 2 Q. In his own lab is what I mean. 3 A. In his own lab, correct. 4 Q. Okay. It wasn't done in a factory like 5 TVTO is made today, correct? 6 A. It wasn't manufactured by a third party, 7 no. 8 Q. And have you reviewed the original launch 9 plan that Ethicon prepared before the launch of the 10 TVTO? 11 A. I went through a few papers because I 12 believe it's included in that binder, and I reviewed 13 them probably, I saw it about a year ago. 14 Q. Okay, and do you know the original launch 15 plan Ethicon had was that they were going to do 16 clinical studies before the TVTO was launched? 17 A. I can't recall specifically they were 18 deciding to do clinical studies on TVTO. 19 Q. I'll make that representation to you. 20 You don't have any reason to dispute that, do you? 21 A. No, no reason to one way or the other. 22 Q. And if the original launch plans 23 anticipated Ethicon was going to conduct its own or 24 independent clinical trials before the launch of TVTO, 25 you would have no objection to that, would you?</p>

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<p>1 A. I would have no objection to, to, to</p> <p>2 that.</p> <p>3 Q. So, because that would be the responsible</p> <p>4 thing to do, wouldn't it?</p> <p>5 MS. GALLAGHER: Object to form.</p> <p>6 A. No, they'll have their reasons to conduct</p> <p>7 their studies, and they have their, their own</p> <p>8 justifications to do whatever trial they may think. I</p> <p>9 believe that what, what determined that was what their</p> <p>10 interaction was between what was established between</p> <p>11 the FDA and Ethicon at that time.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. And that's not really my question, Dr.</p> <p>14 Sepulveda. My question is, you would agree with me</p> <p>15 that the plan to do clinical trials before launching a</p> <p>16 product is a responsible thing to do, that plan itself,</p> <p>17 theoretically?</p> <p>18 A. In general terms, you could say that</p> <p>19 doing clinical trials is a good idea, as long as those</p> <p>20 clinical trials don't put unnecessary subjects to</p> <p>21 demonstrate things that have already been demonstrated.</p> <p>22 Q. Okay. And that's why you normally want</p> <p>23 to do clinical trials, right? You want to build a body</p> <p>24 of science that supports the safety and efficacy of</p> <p>25 your product, correct?</p>	<p>1 to the launch of the TVT is an Ethicon decision and you</p> <p>2 have no idea why they didn't do it?</p> <p>3 A. That's going to be an Ethicon decision</p> <p>4 alone in their interaction with the FDA.</p> <p>5 Q. Should the decision to not do clinical</p> <p>6 trials ever be based on simply wanting to rush your</p> <p>7 product to market? Should that ever be a basis not to</p> <p>8 do a clinical trial?</p> <p>9 MS. GALLAGHER: Object to form.</p> <p>10 A. No, I think that --</p> <p>11 THE WITNESS: Did you get that objection?</p> <p>12 MR. FREESE: She got it, don't worry.</p> <p>13 She's a big girl. You worry about you, she'll</p> <p>14 worry about her.</p> <p>15 A. The decision, I believe whenever there</p> <p>16 are products like this that are innovative, that that</p> <p>17 decision is going to be again, what I already said, I'm</p> <p>18 not going to repeat, I mean, I will repeat what I</p> <p>19 already said, between Ethicon and the FDA, but it's</p> <p>20 also determined internally by Ethicon, by the different</p> <p>21 branches that are input in a project, because you may</p> <p>22 have marketing individuals, you may have sales</p> <p>23 individuals, you will have scientific individuals, you</p> <p>24 have engineers, medical liaisons, so you cannot, you</p> <p>25 cannot just point to one area. I believe that in every</p>
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<p>1 A. Before I continue, I may have said</p> <p>2 unnecessary subjects. I mean as long as it doesn't put</p> <p>3 subjects through unnecessary risks. That's what I</p> <p>4 meant on my answer.</p> <p>5 Q. Yes, sir.</p> <p>6 A. And following with your question?</p> <p>7 MR. FREESE: Would you read back my</p> <p>8 question? I'm sorry.</p> <p>9 THE COURT REPORTER: And that's why you</p> <p>10 normally want to do clinical trials, right?</p> <p>11 You want to build a body of science that</p> <p>12 supports the safety and efficacy of your</p> <p>13 product, correct?</p> <p>14 A. Yes, science built up on previous</p> <p>15 studies.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. And you know that those clinical trials</p> <p>18 never occurred, correct?</p> <p>19 A. I am not aware of those clinical trials</p> <p>20 happening.</p> <p>21 Q. And you don't know the reason why they</p> <p>22 didn't occur, correct?</p> <p>23 A. No, I don't know the reason.</p> <p>24 Q. You said for whatever, whatever reason</p> <p>25 Ethicon had for not doing those clinical trials prior</p>	<p>1 company, every device company, there's going to an</p> <p>2 interaction between all these different individuals</p> <p>3 deciding which, which product gets the studies done.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. And I'm not quibbling with you about</p> <p>6 that, Doctor. My question was quite different. Do you</p> <p>7 agree with me, generally speaking, that, that a</p> <p>8 responsible medical device company shouldn't forgo</p> <p>9 clinical trials simply to rush their product onto the</p> <p>10 market? That's my only question.</p> <p>11 MS. GALLAGHER: Object to form.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. That would not be the responsible thing</p> <p>14 to do. You agree with that?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. It's going to be a decision of the</p> <p>17 company, but in general, in general, you don't, you</p> <p>18 don't rush things. You don't rush decisions for</p> <p>19 surgery, you don't rush decisions to place or take out</p> <p>20 implants. You don't rush in general any of these</p> <p>21 decisions.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. And if the decision to forgo clinical</p> <p>24 trials was simply an economic decision and not based on</p> <p>25 safety or efficacy, we can agree that that would be</p>

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<p>1 something that Dr. Sepulveda would be critical of?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. If anything that is motivated purely by</p> <p>4 economics, it belongs in a different arena and not</p> <p>5 health care.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Thank you. Doctor, this is sort of a</p> <p>8 question we had started the last hour, but other than</p> <p>9 the life care plan, you said that you prepared the</p> <p>10 entirety of this report. Is that correct?</p> <p>11 A. Yes.</p> <p>12 Q. Did you prepare all the footnotes, too?</p> <p>13 A. Yes, I did, I did, I did prepare those,</p> <p>14 those papers.</p> <p>15 Q. And the reason I was curious is because</p> <p>16 the reports and the footnotes have a remarkable</p> <p>17 similarity to doctors from all over the country that</p> <p>18 work for Ethicon, Dr. Permugia and Dr. Grier and Dr.</p> <p>19 Flynn, I mean, we've got these reports and it's</p> <p>20 remarkable how similar your work is and their work.</p> <p>21 A. I can tell you this, I spent a lot of</p> <p>22 time sitting down and writing. It has, there were a</p> <p>23 few other things that were added to it, there were</p> <p>24 things that have been edited by me on consultation with</p> <p>25 the attorneys, but there's, there's no attorney that is</p>	<p>1 Q. My question is, was any of this report</p> <p>2 cut and pasted from any other report, or was this all</p> <p>3 original work product as of March 23rd, 2016?</p> <p>4 A. No, my report on TVTO is my report on</p> <p>5 TVTO, and if it looks like Christina Permugia's report</p> <p>6 or whoever report, it's what's available there. There</p> <p>7 are no more papers.</p> <p>8 Q. But what I'm saying is this, I won't find</p> <p>9 any, any language in your report that, in any report</p> <p>10 prior to March 23rd, 2016, correct, because this is all</p> <p>11 your work product, so I won't be able to go and find</p> <p>12 any reports prepared by you that looks identical, in</p> <p>13 fact is identical in the entire report, because you</p> <p>14 created this on March 23rd, 2016, correct?</p> <p>15 MS. GALLAGHER: Object to form.</p> <p>16 A. I did not create this on March 23rd.</p> <p>17 This has been written and reviewed over the last year</p> <p>18 and a half, two years.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. When did you start writing your Ramirez</p> <p>21 report?</p> <p>22 A. Over a year ago.</p> <p>23 Q. How many hours do you have in the Ramirez</p> <p>24 matter?</p> <p>25 A. Lot of hours. I mean, this is probably</p>
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<p>1 going to bring out a report that I don't, I don't</p> <p>2 approve.</p> <p>3 Q. I'm not saying you don't approve, but, I</p> <p>4 mean, you sat down and actually put all these footnotes</p> <p>5 in your report?</p> <p>6 A. Yeah, actually the footnotes, I remember</p> <p>7 exactly going through the two papers on the frequency</p> <p>8 of these devices, I remember going through all the</p> <p>9 papers that I have saved over time, and there are other</p> <p>10 papers that were given to me about randomized control</p> <p>11 trials. I wrote this, I wrote this just after, just</p> <p>12 after my, my board, my subspecialty board</p> <p>13 certification.</p> <p>14 Q. Did you cut and paste any of this report</p> <p>15 from another report?</p> <p>16 A. No, I wrote a report, I submitted it, and</p> <p>17 then they came back with extra, extra bibliography, but</p> <p>18 I actually submitted a bibliography.</p> <p>19 Q. Okay, you said they came back with a</p> <p>20 bibliography. You're talking about the footnotes,</p> <p>21 correct?</p> <p>22 A. No, if there's a footnote, if there's a</p> <p>23 citation, there's a citation, I look at these</p> <p>24 citations, and the ones that were submitted, I look at</p> <p>25 them before they came.</p>	<p>1 the case that has taken the longest number of hours.</p> <p>2 Q. And so what is that?</p> <p>3 A. I put it together and I submitted as a</p> <p>4 whole group. Let me tell you, when I started seeing</p> <p>5 this, this, these cases, I had like four or five cases</p> <p>6 that I was reviewing, and, then, I was asked to do a</p> <p>7 report on Ramirez. There were other cases that did not</p> <p>8 require a report. That's how I know that I, I recall</p> <p>9 sitting weekends and going, and writing this.</p> <p>10 Q. I just haven't seen a Ramirez invoice.</p> <p>11 Have you prepared one?</p> <p>12 A. I believe that there are a few with</p> <p>13 Ramirez numbers.</p> <p>14 Q. But do you have a total Ramirez invoice</p> <p>15 somewhere?</p> <p>16 A. They were submitted last -- well, that's,</p> <p>17 that's, there was a time in which I say no, we want you</p> <p>18 to put for each specific case, and that's when I</p> <p>19 started doing it, a few months ago, that was for</p> <p>20 Ramirez, and I was here with, with Mr. Schnel last week</p> <p>21 and he had, he had those documents.</p> <p>22 Q. Do you have your Ramirez invoice with</p> <p>23 you?</p> <p>24 A. No.</p> <p>25 MS. GALLAGHER: You already have them.</p>

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<p>1 They were here we when started the depo.</p> <p>2 MR. FREESE: Where are they?</p> <p>3 THE WITNESS: These are my invoices.</p> <p>4 MR. JORDAN: There were two exhibits to</p> <p>5 the letter that Chris Morris sent. One of them</p> <p>6 you were asking to be blown up. The other is</p> <p>7 the invoice.</p> <p>8 MR. FREESE: Right.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. These don't break down Ramirez. Are</p> <p>11 these all Ramirez invoices?</p> <p>12 A. No, there's a group, it's grouping all</p> <p>13 the MDL cases, the most recent ones.</p> <p>14 Q. But you can't tell from these invoices</p> <p>15 what they're for?</p> <p>16 A. Yeah, I just group all the hours on</p> <p>17 there.</p> <p>18 Q. How many hours do you have in your best</p> <p>19 judgment on the Ramirez matter?</p> <p>20 A. I would say over, over a hundred hours.</p> <p>21 Q. Over a hundred hours on Ramirez?</p> <p>22 A. Yeah, easily.</p> <p>23 Q. And that doesn't include your MDL time?</p> <p>24 A. Nor my MDL.</p> <p>25 Q. I'm going to mark as the, the cover</p>	<p>1 procedures manuals, there are lab manuals. So this is</p> <p>2 not, there are people looking over each other's</p> <p>3 shoulders on research projects. So that's what I call,</p> <p>4 what I call about the methodology is not only the</p> <p>5 methodology for the randomized control trial but also</p> <p>6 the surveillance on it.</p> <p>7 Q. Who was overlooking Dr. Ulmsten's study,</p> <p>8 for example, on TVT? Who is looking over his shoulder?</p> <p>9 A. I don't know who was looking at him.</p> <p>10 Q. Nobody was. You know that, don't you?</p> <p>11 A. No, I don't.</p> <p>12 Q. You realize that nobody was overlooking</p> <p>13 Ulmsten's studies?</p> <p>14 A. No, I don't know that.</p> <p>15 Q. Well, can you name me one person who</p> <p>16 oversaw what Dr. Ulmsten prepared?</p> <p>17 A. No, I just don't know who overlooked.</p> <p>18 Q. Did you ever look at the patient level</p> <p>19 data for Dr. Ulmsten?</p> <p>20 A. No.</p> <p>21 Q. Did you know that Ethicon never even</p> <p>22 looked at the patient data for TVT studies that Ulmsten</p> <p>23 did?</p> <p>24 A. No, I do not know how Ulmsten conducted</p> <p>25 his research, his research project.</p>
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<p>1 letters from, the payments from Ethicon and the</p> <p>2 invoices here as Exhibit 7 to your deposition. Okay?</p> <p>3 A. Okay.</p> <p>4 (Plaintiff's Exhibit No. 7 was marked for</p> <p>5 identification.)</p> <p>6 BY MR. FREESE:</p> <p>7 Q. When doing your report, Dr. Sepulveda,</p> <p>8 did you attempt to look and see how many of the authors</p> <p>9 that you were citing in support of your opinions were</p> <p>10 paid consultants by Ethicon?</p> <p>11 A. No.</p> <p>12 Q. Do you even know how many of these</p> <p>13 authors you cited are paid consultants of Ethicon?</p> <p>14 A. No.</p> <p>15 Q. And were paid consultants at the time</p> <p>16 they wrote their reports?</p> <p>17 A. I do not know that.</p> <p>18 Q. Is that a fact of no consideration of</p> <p>19 yours, you don't care?</p> <p>20 A. No, the methodology takes care of</p> <p>21 whatever bias to be introduced.</p> <p>22 Q. Well, assuming one knew what the</p> <p>23 methodology was.</p> <p>24 A. Yes, there's a methodology, there's</p> <p>25 auditing on research projects, there's supervision,</p>	<p>1 Q. Am I correct that you have not looked at</p> <p>2 the patient level data of any of these authors that</p> <p>3 you're citing in your report?</p> <p>4 A. No, that's not correct. I have looked</p> <p>5 at, at these reports and I look at the methodology that</p> <p>6 they have used.</p> <p>7 Q. I'm not asking that. I'm talking about,</p> <p>8 I know you've looked at the methodology. Have you</p> <p>9 looked at the patient level data that the authors were</p> <p>10 looking at when they write these reports?</p> <p>11 A. Define patient level data.</p> <p>12 Q. The actual data that's collected at the</p> <p>13 sites for these trials that are being performed.</p> <p>14 A. How it was collected?</p> <p>15 Q. Yes, sir. Have you ever gotten the</p> <p>16 patient level data of any of these studies?</p> <p>17 A. No, it's not described on the report on</p> <p>18 any papers, any research papers.</p> <p>19 Q. You simply take what the authors say and</p> <p>20 give credit to what they say, assuming that they have</p> <p>21 given credible, reliable, unbiased results, correct?</p> <p>22 A. They -- I don't assume. I read the</p> <p>23 papers, and I read papers that have more accuracy than</p> <p>24 others in methodology, but that's why there's a section</p> <p>25 on methodology on each paper.</p>

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<p>1 Q. And you see what the methodology is and</p> <p>2 then read it, decide you like it, and then cite it?</p> <p>3 A. I decide if I find it accurate, yes.</p> <p>4 Q. You say on page 4 of your report:</p> <p>5 Overall, there are over 100 randomized control trials</p> <p>6 that have accumulated and countless more cohort studies</p> <p>7 on TVT and TVTO. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. We can agree, you've lumped TVT and TVTO</p> <p>10 there in that sense together, have you not?</p> <p>11 A. Yes.</p> <p>12 Q. And we've agreed that they're two</p> <p>13 different products, correct?</p> <p>14 A. The insertion is different.</p> <p>15 Q. And they're different products?</p> <p>16 A. They are different products because the</p> <p>17 insertion is different, the needles are different.</p> <p>18 Q. And they have different clearance</p> <p>19 applications, correct?</p> <p>20 A. They have different clearance</p> <p>21 applications.</p> <p>22 Q. The TVT was cleared using ProteGen as the</p> <p>23 predicate product, correct?</p> <p>24 A. Yes.</p> <p>25 Q. So when you say a hundred randomized</p>	<p>1 Q. Why don't you grab that.</p> <p>2 MR. FREESE: Let's go ahead and mark</p> <p>3 that, let's slap Exhibit 8 on there.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. And would you tell us what you're looking</p> <p>6 at there, sir?</p> <p>7 A. I'm looking at the review article from</p> <p>8 Neurourology and Urodynamics from 2011, and I should</p> <p>9 have an updated version in my reliance list.</p> <p>10 Q. Okay. Do you know whether or not this</p> <p>11 was the one that the FDA was looking at in the white</p> <p>12 paper?</p> <p>13 A. Most likely that's the one that they</p> <p>14 were, they were looking at.</p> <p>15 Q. Because it's 2011?</p> <p>16 A. Exactly. I don't have the 2016 easily</p> <p>17 marked in here. I know it's in this pile.</p> <p>18 Q. Let's try to work on this. If you think</p> <p>19 it's substantially different, then we can maybe find it</p> <p>20 during a break. Does Exhibit 8 answer your question</p> <p>21 that I -- does it answer my question? Do you want me</p> <p>22 to remind you what my question is?</p> <p>23 A. It's how many randomized control trials</p> <p>24 are on TVTOs?</p> <p>25 Q. Yes, sir.</p>
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<p>1 control trials, we can agree that you didn't mean to</p> <p>2 suggest to the reader of this that there are over 100</p> <p>3 randomized control trials of TVTOs. We can agree on</p> <p>4 that, can we not?</p> <p>5 A. No, of TVT and TVTO.</p> <p>6 Q. Yeah. So, my question to you is, you</p> <p>7 agree with me that there are not over 100 randomized</p> <p>8 control trials of TVTO, correct?</p> <p>9 A. That is correct.</p> <p>10 Q. And if you then looked and said I want to</p> <p>11 know how many -- first of all, do you know how many</p> <p>12 randomized control trials of TVTO exists?</p> <p>13 A. It's in the Cochrane paper, and I do have</p> <p>14 an abbreviated portion of the Cochrane and I can refer</p> <p>15 to it.</p> <p>16 Q. All right, without referring, do you have</p> <p>17 a judgment how many randomized control trials of TVTO</p> <p>18 exists?</p> <p>19 A. No, it's in the Cochrane. If I would</p> <p>20 have asked, if a patient would come and ask me that</p> <p>21 question I would say I will have to look at the</p> <p>22 Cochrane review.</p> <p>23 Q. Do you have the Cochrane review with you</p> <p>24 right now?</p> <p>25 A. Yes.</p>	<p>1 A. Okay, they found 24 trials.</p> <p>2 Q. Where are you looking?</p> <p>3 A. Right here.</p> <p>4 Q. Okay. Are you saying 24 trials address</p> <p>5 the comparison of transobturator route versus</p> <p>6 retropubic route?</p> <p>7 A. Yes.</p> <p>8 Q. And then it has those cited. Okay, now,</p> <p>9 let me ask you further, of these 24, of these 24</p> <p>10 randomized control studies, they weren't all TVTO</p> <p>11 studies, were they? They were comparing retropubic</p> <p>12 versus obturator approach, correct?</p> <p>13 A. Right.</p> <p>14 Q. So, of those 24, not even all 24 of those</p> <p>15 are dealing with Ethicon's TVTO, is that correct?</p> <p>16 A. No, there's, to do a randomized control</p> <p>17 trial, if it would be just TVTO, it would be a cohort</p> <p>18 study. If it's a randomized control trial, you have to</p> <p>19 have two arms, and with those two arms classically what</p> <p>20 we have is the retropubic and the, and the TVTO. The</p> <p>21 biggest study on that is the TOMUS, T-O-M-U-S, the</p> <p>22 TOMUS trial.</p> <p>23 Q. But my question is, some of these 24</p> <p>24 studies are not even studying the Ethicon TVTO, they</p> <p>25 are simply comparing midurethral slings that are using</p>

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<p>1 an obturator approach, it may not even be Ethicon's</p> <p>2 products being studied, correct?</p> <p>3 A. There are two, they made two comparisons</p> <p>4 in the Cochrane data review. They made a comparison</p> <p>5 between transobturator slings and they made a</p> <p>6 comparison between retropubic and transobturator</p> <p>7 slings.</p> <p>8 Q. And not necessarily even Ethicon's</p> <p>9 transobturator slings, correct?</p> <p>10 A. Yeah, they compared different ones.</p> <p>11 Q. And, so, am I correct, you cannot sit</p> <p>12 here today, Dr. Sepulveda, and tell me how many</p> <p>13 randomized control studies have been done looking at</p> <p>14 Ethicon's TVTO? Can you agree that you can't tell me</p> <p>15 that number?</p> <p>16 A. I can, I can say for certain, without</p> <p>17 looking into the long version, this is the short</p> <p>18 version of the Cochrane data review, I can say with</p> <p>19 accuracy the TOMUS trial.</p> <p>20 Q. One?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. I'll mark Exhibit 9 to your</p> <p>23 deposition, which is the, do you recognize that as the</p> <p>24 white paper?</p> <p>25 A. Yes, the FDA Executive Summary.</p>	<p>1 A. Yes, they did have an opinion here.</p> <p>2 Q. And it says in the first paragraph, under</p> <p>3 conclusion, safety of mesh used in repair of stress</p> <p>4 urinary incontinence based on published literature. Do</p> <p>5 you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Quote, "The Cochrane reviews are limited</p> <p>8 in the ability to fully evaluate the safety of profile</p> <p>9 of the surgical mesh used in SUI patients. The main</p> <p>10 objective of these reviews is to evaluate the</p> <p>11 effectiveness of the SUI procedures using randomized</p> <p>12 control trials that have compared a mesh procedure to</p> <p>13 another approach." Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. So, the FDA was criticizing the</p> <p>16 reliability of the Cochrane reviews from a safety</p> <p>17 standpoint, correct?</p> <p>18 MS. GALLAGHER: Object to form.</p> <p>19 A. That is, that is, that is correct. They</p> <p>20 disagree with the methodology.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. I accurately read what the FDA said about</p> <p>23 the Cochrane reviews that you are relying on, correct?</p> <p>24 A. Yes, they, I think that, when you look --</p> <p>25 Q. Hold on. I don't mean to cut you off,</p>
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<p>1 (Plaintiff's Exhibit No. 9 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. FREESE:</p> <p>4 Q. And you've looked and relied upon this,</p> <p>5 did you not, in forming your opinions?</p> <p>6 A. I read it and it just allow me to</p> <p>7 understand. There was no specific cite on my opinion</p> <p>8 that refers to, to that paper.</p> <p>9 Q. But you actually showed up to your</p> <p>10 deposition with a highlighted copy of it, did you not?</p> <p>11 A. No, I -- yes, I actually did have a</p> <p>12 highlight copy, but the only data, the only place in</p> <p>13 which I refer to the Executive Summary from my report</p> <p>14 is when I, when I speak about the MAUDE database.</p> <p>15 Q. Let's talk about something different,</p> <p>16 though. Let me show you Exhibit 9, page 42, of the FDA</p> <p>17 Executive Paper.</p> <p>18 Now, you've -- and before we get to that,</p> <p>19 your testimony is you relied on the Cochrane report in</p> <p>20 forming your opinions today about the safety and</p> <p>21 efficacy of TVTO, am I correct?</p> <p>22 A. And the Cochrane report and the TOMUS</p> <p>23 trial and the Tommaselli analysis.</p> <p>24 Q. And the FDA had some comments about the</p> <p>25 Cochrane review, did it not?</p>	<p>1 but I'm simply asking you, did I accurately read to you</p> <p>2 just now what the FDA's conclusion was of the Cochrane</p> <p>3 reviews?</p> <p>4 A. That's what they described, yes.</p> <p>5 Q. If you'll drop down three paragraphs, it</p> <p>6 says, quote, "The Cochrane reviews did however identify</p> <p>7 noteworthy differences between mesh procedures and open</p> <p>8 colposuspension. The risk of perioperative</p> <p>9 complications favored colposuspension compared to all</p> <p>10 sling procedures combined, and the risk of voiding</p> <p>11 dysfunction was similar between colposuspension and the</p> <p>12 TVT sling." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Did I read that correctly?</p> <p>15 A. You read that. I didn't follow word by</p> <p>16 word, but you...</p> <p>17 Q. Okay, and that's, that's contrary to the</p> <p>18 opinion that you've expressed in your report, is it</p> <p>19 not?</p> <p>20 A. That's, the Cochrane review and the most</p> <p>21 recent Cochrane review and the TOMUS report are what's</p> <p>22 used in my report, and there's, I was looking for my</p> <p>23 2015 Cochrane review, and I just found it.</p> <p>24 Q. Okay, and we'll get to that, but let me</p> <p>25 finish my question here. You agree with me that the</p>

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<p>1 FDA concluded that the, the Cochrane reviews that you</p> <p>2 have relied on were noteworthy because they found, in</p> <p>3 the view of the FDA, that the risks of perioperative</p> <p>4 complications made mesh less safe compared to</p> <p>5 colposuspension, correct?</p> <p>6 A. But that's not what it says on the</p> <p>7 Cochrane review.</p> <p>8 Q. That's what the FDA concluded after</p> <p>9 reading the Cochrane review, correct?</p> <p>10 A. Yes, but I don't know how they came to</p> <p>11 that conclusion.</p> <p>12 Q. And you understand, Doctor, what the FDA</p> <p>13 was doing in 2011 when they prepared this white paper,</p> <p>14 they were doing a systematic review of all known</p> <p>15 literature, were they not?</p> <p>16 MS. GALLAGHER: Object to form.</p> <p>17 A. Yes, but that's not what's been published</p> <p>18 on the summary.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. But what I'm saying, you understand</p> <p>21 that's what the FDA undertook to do? They undertook to</p> <p>22 independently collect all known literature on the</p> <p>23 safety and efficacy of midurethral slings and draw some</p> <p>24 conclusions from those studies, correct?</p> <p>25 A. If they did a systematic review, I have</p>	<p>1 A. This is not a report of a systematic</p> <p>2 review. This is an executive summary.</p> <p>3 Q. Have you looked at the systematic review?</p> <p>4 A. I have not seen a systematic review.</p> <p>5 Q. So you're not saying that the systematic</p> <p>6 review came to any different conclusion than what the</p> <p>7 summary did, correct?</p> <p>8 A. Well, I have not seen it.</p> <p>9 Q. Okay. But you disagree with the</p> <p>10 conclusions they reached regarding the Cochrane</p> <p>11 reviews?</p> <p>12 A. Yes, I do disagree.</p> <p>13 Q. Okay. So, in your view, at least in this</p> <p>14 respect, Dr. Sepulveda, you would say that the FDA got</p> <p>15 it wrong in their conclusion regarding what the</p> <p>16 Cochrane reviews showed about complications from</p> <p>17 midurethral slings, correct?</p> <p>18 A. Yes, and I base my, my answer on the</p> <p>19 last, on the last statement on the review article, that</p> <p>20 says that monofilament tape has significantly higher</p> <p>21 objective cure rates, and the obturator use wasn't less</p> <p>22 favorable than retropubic, but only on an 84 to 88</p> <p>23 percent --</p> <p>24 Q. That's on the cure rates, though.</p> <p>25 A. That's on cure rate.</p>
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<p>1 not seen any publication about the systematic review</p> <p>2 made by the FDA, because the document that you have in</p> <p>3 front of you is an executive summary, it's not a</p> <p>4 systematic review report.</p> <p>5 Q. Would you look at the second paragraph,</p> <p>6 sir?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Quote, "The FDA's systematic</p> <p>9 literature review found that the weighted average rates</p> <p>10 of urinary problems, re-surgery rates and perioperative</p> <p>11 organ perforations were similar to overall rates</p> <p>12 presented in published meta-analyses and systematic</p> <p>13 reviews." Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. They're saying they did a systematic</p> <p>16 literature review.</p> <p>17 A. Yes, they say that.</p> <p>18 Q. Do you dispute that they did a systematic</p> <p>19 literature review?</p> <p>20 A. I don't dispute they did it. I just have</p> <p>21 not seen the document.</p> <p>22 Q. Well, we're looking at the document.</p> <p>23 A. No, this is not a report of a systematic</p> <p>24 review.</p> <p>25 Q. This is the report of the review.</p>	<p>1 Q. We're talking about complications right</p> <p>2 now.</p> <p>3 A. Yes, we go through that. However, there</p> <p>4 were less voiding dysfunction, blood loss, bladder</p> <p>5 perforation with the obturator route.</p> <p>6 Q. Compared to what?</p> <p>7 A. Compared to colposuspension, pubovaginal</p> <p>8 slings and retropubic procedures.</p> <p>9 Q. Doctor, let's move up a paragraph here.</p> <p>10 In the Cochrane review, minimally-invasive synthetic</p> <p>11 suburethral sling operation appeared to be as effective</p> <p>12 as open retropubic colposuspension, correct?</p> <p>13 A. Yes.</p> <p>14 Q. That's talking about efficacy, correct?</p> <p>15 A. Yes.</p> <p>16 Q. But that it had significantly more</p> <p>17 bladder perforations, correct?</p> <p>18 A. There were more bladder perforations when</p> <p>19 we compare, when you compare colposuspensions with</p> <p>20 retropubic slings.</p> <p>21 Q. Doctor, I'm going to mark as Exhibit 10</p> <p>22 to your deposition the actual appendix to the published</p> <p>23 review of literature that we've looked at with the FDA.</p> <p>24 (Plaintiff's Exhibit No. 10 was marked</p> <p>25 for identification.)</p>

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<p>1 BY MR. FREESE:</p> <p>2 Q. Do you see, you've seen this was actually</p> <p>3 part of the Executive Summary. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it says the FDA evaluated the</p> <p>6 peer-reviewed scientific literature to revisit the</p> <p>7 fundamental question of safety and effectiveness for</p> <p>8 surgical mesh for POP and SUI, correct?</p> <p>9 A. Yes.</p> <p>10 Q. A systematic literature review was</p> <p>11 conducted by searching the PubMed database from</p> <p>12 January, 1996, to April, 2011. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. I won't read you all this, but this says</p> <p>15 what the FDA actually did, correct?</p> <p>16 A. Yes.</p> <p>17 Q. You have no reason to dispute that they</p> <p>18 actually did what they say here in Exhibit 10?</p> <p>19 A. I have no reason to dispute that's what</p> <p>20 they do.</p> <p>21 Q. You just dispute some conclusions they</p> <p>22 reached?</p> <p>23 A. Yes, I think that the Cochrane review,</p> <p>24 with all the possible limitations that any study would</p> <p>25 have, have less limitations than the FDA executive</p>	<p>1 this, the fact that we're looking at an executive</p> <p>2 summary and the fact that we don't have a systematic</p> <p>3 review publication just speaks for itself in looking at</p> <p>4 the overreaching of these conclusions.</p> <p>5 Q. And this goes on to say, quote, "The FDA</p> <p>6 is concerned that the safety outcomes may not have been</p> <p>7 comprehensively evaluated by the randomized control</p> <p>8 trial to date and that the safety of SUI repair with</p> <p>9 mesh needs to be further considered in evaluating the</p> <p>10 overall risk-to-benefit profile of these products." Do</p> <p>11 you see that?</p> <p>12 A. And it was actually further considered.</p> <p>13 Q. Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. Okay, and do you agree with that</p> <p>16 conclusion?</p> <p>17 A. Yes, it needs to be further considered.</p> <p>18 I do agree with that. And it was further considered.</p> <p>19 Q. And you agree that the comprehensive</p> <p>20 review of the RCTs may not have been able to</p> <p>21 comprehensively capture all of the safety data on the</p> <p>22 midurethral slings?</p> <p>23 A. No, the RCTs will have established</p> <p>24 benchmark for safety.</p> <p>25 Q. Well, the conclusion was that they didn't</p>
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<p>1 report.</p> <p>2 Q. Even the FDA said the Cochrane review</p> <p>3 results were only of moderate value, did they not?</p> <p>4 A. Well, there's no standardization of</p> <p>5 statistical analysis done in concluding that, if they</p> <p>6 say that.</p> <p>7 Q. Well, they do that say that, don't they?</p> <p>8 They said that the strength of the Cochrane data is</p> <p>9 moderate. That's how way they described it, did they</p> <p>10 not?</p> <p>11 A. Yes, most of it is not moderate.</p> <p>12 Q. And, Doctor, back to page 43 of the</p> <p>13 executive study.</p> <p>14 A. Yes, I have that right here.</p> <p>15 Q. The FDA said that in the systematic</p> <p>16 review of the literature conducted by the FDA and based</p> <p>17 on adverse event reports in the MAUDE database, there's</p> <p>18 a potential for serious complications with mesh</p> <p>19 products indicated for SUI repair. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Do you disagree with that?</p> <p>22 A. No, they actually table it, they actually</p> <p>23 got the frequency, and they actually mentioned the</p> <p>24 limitations of the MAUDE database. So, that's, I find</p> <p>25 this, this statement to be overreaching. I think that</p>	<p>1 comprehensively gather the safety data, the RCTs</p> <p>2 didn't.</p> <p>3 A. That's the executive summary conclusion,</p> <p>4 but that's not the conclusion of the mesh analysis done</p> <p>5 by the Cochrane review.</p> <p>6 Q. Again, that's the conclusion of the FDA</p> <p>7 that you disagree with?</p> <p>8 A. That's what they state and I disagree</p> <p>9 with it, yes.</p> <p>10 Q. And let me just ask one more question and</p> <p>11 we'll move on to something else. So, now that we've</p> <p>12 gone through this discussion here, Dr. Sepulveda, we</p> <p>13 can agree that the only long-term randomized controlled</p> <p>14 study of TVTO that you're aware of is the TOMUS study?</p> <p>15 A. No, I am aware of the, of the study done</p> <p>16 by Cloe in 2013, which is a randomized control trial of</p> <p>17 the TVT and TOT. I'm also aware of the RCT comparing</p> <p>18 TVT and TVTO of Aniulene, which is a prospective</p> <p>19 randomized control trial of TVTO and TVT.</p> <p>20 Q. Over what period of time?</p> <p>21 A. On 264 women.</p> <p>22 Q. For how long?</p> <p>23 A. For -- I cannot answer that question</p> <p>24 based on this, on what I have.</p> <p>25 Q. So you can't tell if it's a long-term</p>

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<p>1 study or not?</p> <p>2 A. Well, it's a randomized control trial</p> <p>3 that looks at safety of the TVTO. I also have, and</p> <p>4 these are from the new Cochrane review which I found,</p> <p>5 the one from 2015. I have TVTO being compared to TOT</p> <p>6 in 2008.</p> <p>7 Q. How long?</p> <p>8 A. That's a three month, three month.</p> <p>9 Q. That's not a long-term study, is it?</p> <p>10 A. No, there are other longer-term studies.</p> <p>11 Q. But we can agree that three months is not</p> <p>12 by anybody's definition a long-term study, correct?</p> <p>13 A. No, that's a study just about safety.</p> <p>14 Q. First of all, you're looking at the 2015</p> <p>15 Cochrane review?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. As you sit here today, Doctor, can</p> <p>18 you tell me how many long-term randomized control</p> <p>19 trials there are of TVTO --</p> <p>20 MS. GALLAGHER: Object to form.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. -- whose primary end point is safety?</p> <p>23 MS. GALLAGHER: Object to form.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. How many of those exist?</p>	<p>1 Q. Okay, and in those five-, seven- and</p> <p>2 ten-year trials, the primary objective was safety. Is</p> <p>3 that correct?</p> <p>4 A. Safety.</p> <p>5 Q. As opposed to efficacy?</p> <p>6 A. Safety and efficacy is evaluated on both,</p> <p>7 but now that you mention, the TOMUS trial was safety</p> <p>8 and efficacy. The Tommaselli medium-term and long-term</p> <p>9 following midurethral slings, which is a systematic</p> <p>10 review of meta-analysis as the highest level of</p> <p>11 evidence, was at 36 months and at 60 months.</p> <p>12 Q. Okay. So, there's one at 60 months,</p> <p>13 correct?</p> <p>14 A. I can, I can continue looking, looking</p> <p>15 for it, on the different ones, but --</p> <p>16 Q. That's fine, and this is not a memory</p> <p>17 test, and I'm sure your lawyer will be happy to walk</p> <p>18 you through when we get to the courthouse, but just</p> <p>19 sitting here right now, you can't name me one study</p> <p>20 that meets the parameters I just defined, correct?</p> <p>21 A. Yes, I just, I just mentioned them to</p> <p>22 you.</p> <p>23 Q. Which, TOMUS?</p> <p>24 A. Tommaselli.</p> <p>25 Q. Tommaselli?</p>
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<p>1 A. I'm just looking through them.</p> <p>2 Q. Listen to my question. How many of those</p> <p>3 are long-term studies, what I mean by that, five years</p> <p>4 or more, how many long-term, controlled, randomized</p> <p>5 controlled studies of TVTO exist, five years or</p> <p>6 greater, with the primary end point of safety? How</p> <p>7 many of those studies?</p> <p>8 A. Well, I've already gone through three of</p> <p>9 them, because there's also the Chen study.</p> <p>10 Q. How long is that?</p> <p>11 A. This was 12 to 24 months.</p> <p>12 Q. That's not five years. Doctor, listen to</p> <p>13 my question. Close the book, you've got to look at me</p> <p>14 and listen to my question because I think you're</p> <p>15 getting distracted. Do you know how many randomized</p> <p>16 controlled studies, long term, by which I mean longer</p> <p>17 than five years, and whose primary end point was</p> <p>18 safety, are there dealing with TVTO?</p> <p>19 A. No, I do not, I do not recall the</p> <p>20 specific number of them and I know there are trials at</p> <p>21 five years, seven years, and ten years.</p> <p>22 Q. Okay.</p> <p>23 A. There are trials in here, and I have it</p> <p>24 in my reliance list, but if you're asking me just to</p> <p>25 recall as a memory test, no, I do not recall that.</p>	<p>1 A. TOMUS trial, which is the best designed</p> <p>2 and most accurate trial that have ever been done with</p> <p>3 TVT and TVTO. There's the, there's Chen.</p> <p>4 Q. Chen was five years or greater?</p> <p>5 A. That's less.</p> <p>6 Q. Doctor, we're not getting -- it has to be</p> <p>7 five years or greater. That's all I'm asking you. How</p> <p>8 many studies, TVTO, five years or longer, that study</p> <p>9 the safety of the device?</p> <p>10 MS. GALLAGHER: Object to form.</p> <p>11 A. I, I already say that I cannot recall one</p> <p>12 specific number.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. And we can agree that it's way less than</p> <p>15 a hundred, correct?</p> <p>16 A. It is less than, than a hundred.</p> <p>17 Q. It's way less than 24, is it not?</p> <p>18 A. It might be more than 24 now.</p> <p>19 Q. As you sit here right now, you're unable</p> <p>20 to name one.</p> <p>21 MS. GALLAGHER: Object to form.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. Correct?</p> <p>24 A. I said I cannot recall it.</p> <p>25 Q. That's fine. That's all I want to know.</p>

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<p>1 Sitting here right now, you cannot name one.</p> <p>2 MS. GALLAGHER: Object to form. He's</p> <p>3 already told you about three.</p> <p>4 MR. FREESE: Counsel.</p> <p>5 A. I already told you the studies that I can</p> <p>6 recall, and I looked at them and I gave you my best</p> <p>7 effort to give you that information.</p> <p>8 BY MR. FREESE:</p> <p>9 Q. All right. And of the TVTO studies that</p> <p>10 you rely on, Doctor, can we agree that none of them</p> <p>11 make a distinction between laser cut versus mechanical</p> <p>12 cut?</p> <p>13 A. Yes, that has been established already.</p> <p>14 Q. Even the doctors who did the study don't</p> <p>15 say whether or not the patients they are studying were</p> <p>16 implanted with laser-cut versus mechanical-cut TVTO,</p> <p>17 correct?</p> <p>18 A. That's correct, there's no definition of</p> <p>19 it.</p> <p>20 Q. And you don't know?</p> <p>21 A. No, I don't know because they did not</p> <p>22 disclose it.</p> <p>23 Q. And if there's in fact a clinically</p> <p>24 significant difference in safety between</p> <p>25 mechanically-cut TVTO and laser-cut TVTO, it won't be</p>	<p>1 slings.</p> <p>2 Q. It goes on to say, quote, "Surgical</p> <p>3 experience made clear that patients treated with TVT</p> <p>4 had less voiding dysfunction, less wound complications</p> <p>5 and less retention than the historic numbers from</p> <p>6 patients treated with pubovaginal slings, needle</p> <p>7 procedures or retropubic procedures." Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. You don't cite anything for that</p> <p>10 statement, do you?</p> <p>11 A. No, but I --</p> <p>12 Q. Hold on, I'll ask, you don't cite</p> <p>13 anything for that statement?</p> <p>14 A. No, sir, I don't.</p> <p>15 Q. And you're referring to TVT studies, not</p> <p>16 TVTO studies, correct?</p> <p>17 A. I'm referring to TVT studies and I'm</p> <p>18 referring to TVTO studies.</p> <p>19 Q. Well, it says TVT. The sentence says</p> <p>20 that surgical experience made clear that patients</p> <p>21 treated with TVT. That's a different product than</p> <p>22 TVTO, is it not?</p> <p>23 A. Okay, we keep saying that it's a</p> <p>24 different product. I have the impression that we're</p> <p>25 going to be looking at those different products through</p>
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<p>1 discernable from the studies, will it?</p> <p>2 A. No, it's not discernable from the</p> <p>3 studies. That has not been defined.</p> <p>4 Q. That has what?</p> <p>5 A. That has not been defined.</p> <p>6 Q. Okay. Doctor, would you look at page 14</p> <p>7 of your report?</p> <p>8 A. Yes.</p> <p>9 Q. I just want to ask you real quick, the</p> <p>10 bottom of the first paragraph there, it says no medical</p> <p>11 certification of these complications or diagnostic</p> <p>12 confirmation was required on this report. Do you see</p> <p>13 that?</p> <p>14 A. Yes.</p> <p>15 Q. Would you just -- I don't understand the</p> <p>16 sentence. Can you tell me what that means?</p> <p>17 A. Before we, we saw TVT and before we saw</p> <p>18 TVTO, before we actually saw midurethral slings, the</p> <p>19 quality of the studies were not, were not strong. We,</p> <p>20 we actually saw the first comparison between</p> <p>21 pubourethral slings and colposuspension in the, in the</p> <p>22 Alba trial published in the New England Journal of</p> <p>23 Medicine, but until then there was a very weak, very,</p> <p>24 very small cohort studies establishing the safety and</p> <p>25 efficacy of Burch colposuspensions and pubovaginal</p>	<p>1 the course of the day. So, do you want me to go</p> <p>2 through the, and I'm sure if you want you'll probably</p> <p>3 ask, but in which regard are we defining those</p> <p>4 differently?</p> <p>5 Q. Well, if I said give me a TVT and give me</p> <p>6 a TVTO, we would have to have two different boxes,</p> <p>7 wouldn't we?</p> <p>8 A. Yes.</p> <p>9 Q. Okay, because they're two different</p> <p>10 products, correct?</p> <p>11 A. They're two different products in the</p> <p>12 insertion needles, yes.</p> <p>13 Q. They were cleared in a different way?</p> <p>14 A. They were cleared in a different way.</p> <p>15 Q. They had different predicate products?</p> <p>16 A. Yes.</p> <p>17 Q. That's what I mean by they're different</p> <p>18 products. So, when you're citing a TVT study, that's</p> <p>19 not a study of TVTO, correct?</p> <p>20 A. That's, that's not necessarily a study of</p> <p>21 TVTO. That's a study about the tape.</p> <p>22 Q. That's my point. When you cite a TVT</p> <p>23 study, it's not a study of TVTO, is it?</p> <p>24 A. No, if I cite a TVT study, I'm citing</p> <p>25 that. TVTO is TVTO. But, yes, the surgical experience</p>

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<p>1 showed that there were less complications with</p> <p>2 pubovaginal slings or colposuspensions.</p> <p>3 Q. Against TVT?</p> <p>4 A. Against TVT, and when TVTO was compared</p> <p>5 to TVT, there was less.</p> <p>6 Q. But your sentence doesn't even mention</p> <p>7 TVTO, is my only point.</p> <p>8 A. I did not mention TVTO in that sentence.</p> <p>9 Q. I mean, is the point you're trying to</p> <p>10 make, Dr. Sepulveda, that, that you, you like to use</p> <p>11 TVT and TVTO studies interchangeably because they</p> <p>12 involve the same polypropylene mesh?</p> <p>13 A. Well, there are more similarities than</p> <p>14 differences.</p> <p>15 Q. But is it because they use the same mesh?</p> <p>16 A. No, not necessarily just the same mesh.</p> <p>17 Q. Well, is that one of the reasons why you</p> <p>18 use the studies interchangeably?</p> <p>19 A. Yes, you can actually use one or the</p> <p>20 other, but I don't even need to refer to TVT. TVTO has</p> <p>21 been shown in randomized control trials has been as</p> <p>22 effective and safer than TVT.</p> <p>23 Q. Okay. And, so I guess it would be a fair</p> <p>24 comparison to compare TVT Secur to TVTO, right, because</p> <p>25 it uses the same mesh?</p>	<p>1 BY MR. FREESE:</p> <p>2 Q. Now, Doctor, am I correct that Prolene</p> <p>3 mesh is the mesh that's used in all TVT products,</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And that's the original old construction</p> <p>7 Prolene, correct?</p> <p>8 A. That is the construction of Prolene and,</p> <p>9 and it's to the same degree of crystallinity that the,</p> <p>10 of Prolene sutures.</p> <p>11 Q. I'm not asking about sutures right now,</p> <p>12 we can talk about that in a minute, but am I correct</p> <p>13 that the Prolene that is in the TVTO is the same</p> <p>14 Prolene that was used in Dr. Ulmsten's original TVT</p> <p>15 product?</p> <p>16 A. It's the same construction Prolene. I</p> <p>17 cannot recall if the exact crystallinity or purity or</p> <p>18 analysis from Ulmsten. I don't think that he did that.</p> <p>19 Q. Well, you know that the formulation for</p> <p>20 Prolene mesh has not changed since the original TVT</p> <p>21 produced by Ethicon, correct? And what I'm asking</p> <p>22 there is, the same mesh that's in TVT is in TVTO, is in</p> <p>23 TVT Abbrevio, TVT Secur, TVT Exact. Correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And that is a, that is a</p>
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<p>1 MS. GALLAGHER: Object to form.</p> <p>2 A. We're not talking about TVT Secur now.</p> <p>3 We can talk about how TVT Secur, and I have provided</p> <p>4 testimony before about how TVT Secur shares</p> <p>5 similarities with previous generations of TVTs.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. They share the same mesh, do they not?</p> <p>8 A. They do.</p> <p>9 Q. As does Abbrevio, that has the same mesh?</p> <p>10 A. That has the same mesh, right.</p> <p>11 Q. So, basically, Doctor, on page 14, all</p> <p>12 these numbers and results of studies you're referring</p> <p>13 to, these are all TVT studies, are they not?</p> <p>14 A. These are TVT studies.</p> <p>15 Q. They're not TVTO studies.</p> <p>16 A. And whatever complication might be</p> <p>17 reported from TVT is not going to be higher on TVTO.</p> <p>18 Q. That's not my question, sir. Everything</p> <p>19 you're quoting here in your report are TVT studies, not</p> <p>20 TVTO studies?</p> <p>21 A. These are TVT studies, right.</p> <p>22 MR. FREESE: Let's take about two</p> <p>23 minutes. I want to grab some exhibits real</p> <p>24 quick.</p> <p>25 (Break from 11:35 a.m. to 11:45 a.m.)</p>	<p>1 small-pore, heavyweight mesh, is it not?</p> <p>2 A. No, it's not small pore.</p> <p>3 Q. You think it's a large-pore mesh?</p> <p>4 A. It is a large pore.</p> <p>5 Q. And do you think it's a heavyweight mesh?</p> <p>6 A. It's, in all, of all the applications</p> <p>7 that I use for midurethra, it's a lightweight mesh.</p> <p>8 When it's compared to the meshes for prolapse, it's on</p> <p>9 the heavyweight, it's close to the heavyweight, but not</p> <p>10 at the level that was the old meshes for hernias.</p> <p>11 Q. Well, the old hernia mesh is Prolene,</p> <p>12 correct?</p> <p>13 A. The old hernia mesh is Prolene.</p> <p>14 Q. Okay. So, you're agreeing that the</p> <p>15 Prolene mesh is heavyweight mesh?</p> <p>16 A. The Prolene mesh is heavyweight, yes.</p> <p>17 The Prolene that was initially described that we had 20</p> <p>18 years ago, that's heavyweight.</p> <p>19 Q. Well, what is used today is heavyweight</p> <p>20 mesh, is it not?</p> <p>21 A. No, the fiber is lightweight.</p> <p>22 Q. You think the fiber in the TVTO is</p> <p>23 lightweight?</p> <p>24 A. Yes.</p> <p>25 Q. And you think it's large pore?</p>

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<p>1 A. It's large pore.</p> <p>2 Q. What is the basis for that opinion?</p> <p>3 A. The large pore is over 75 microns, and</p> <p>4 the pore size on the mesh for TVT is 1,200 microns.</p> <p>5 Q. That's an AMI classification that you're</p> <p>6 using?</p> <p>7 A. That's on the AMI classification, which</p> <p>8 we know has its own limitations, but that's the only</p> <p>9 one that we have to compare the, the large pores with</p> <p>10 the small pores.</p> <p>11 Q. The sole basis of you describing Prolene</p> <p>12 as large pore and lightweight is the AMI</p> <p>13 classification?</p> <p>14 A. Yes, on the, on the slings, on the</p> <p>15 monofilament polypropylene slings, this is one of the</p> <p>16 largest pores.</p> <p>17 Q. I'm just asking the sole basis for your</p> <p>18 opinion on that is the AMI classification?</p> <p>19 A. No, that's not the sole basis. It's also</p> <p>20 the fact that it's a large pore, it's over 75 microns,</p> <p>21 and even when you define larger pores at 200, 300, it's</p> <p>22 still a lot larger than that.</p> <p>23 Q. I'm asking you what is your basis for 75</p> <p>24 microns, other than the AMI classification?</p> <p>25 A. For the classification of 75 microns, it</p>	<p>1 company, I wouldn't find any internal documents in</p> <p>2 there saying that Prolene is small pore, heavyweight,</p> <p>3 would I?</p> <p>4 A. That would be the basis of the</p> <p>5 disagreement of the engineers with me. So if there's a</p> <p>6 document in there, I would like to see it.</p> <p>7 Q. I'm asking you, Doctor, if I look through</p> <p>8 here, as you sit here right now, you don't remember</p> <p>9 them supplying you with any internal documents where</p> <p>10 the scientists and the researchers at Ethicon</p> <p>11 repeatedly described their Prolene mesh as heavyweight</p> <p>12 and small pore? It's not in that binder, is it?</p> <p>13 A. I don't recall it being in the binder,</p> <p>14 no.</p> <p>15 Q. And as you sit here, you don't have any</p> <p>16 recollection that they supplied you any such documents</p> <p>17 stating that Prolene is heavyweight and small pore?</p> <p>18 A. No, I do not.</p> <p>19 (Plaintiff's Exhibit No. 11 was marked</p> <p>20 for identification.)</p> <p>21 BY MR. FREESE:</p> <p>22 Q. Now, I'm going to show you what I've</p> <p>23 marked as Exhibit 11 to your deposition. And do you</p> <p>24 see this chart here, Doctor?</p> <p>25 A. Yes, I do see it.</p>
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<p>1 is the AMI classification.</p> <p>2 Q. So, if I say, Doctor, what is the basis</p> <p>3 of your opinion that Prolene mesh is lightweight and</p> <p>4 large pore, you would say AMI classification, correct?</p> <p>5 A. That's, that's the only classification</p> <p>6 that defines pores.</p> <p>7 Q. And you have no other basis for that</p> <p>8 opinion other than that?</p> <p>9 A. I would not have any, any other on that</p> <p>10 specific pore size.</p> <p>11 Q. You understand, Dr. Sepulveda, that the</p> <p>12 engineers at Ethicon disagree with you, do you not?</p> <p>13 A. No, I --</p> <p>14 MS. GALLAGHER: Object to form.</p> <p>15 A. I cannot base, that's an ambiguous</p> <p>16 question. I don't know which way they would disagree</p> <p>17 or what they're saying.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. I'm asking you, have you ever seen any</p> <p>20 internal Ethicon documents describing the Prolene mesh</p> <p>21 as heavyweight and small pore?</p> <p>22 A. They -- no, I don't, I don't, I haven't</p> <p>23 seen anything as small pore.</p> <p>24 Q. Okay. So, if I looked through your TVTO</p> <p>25 company documents selected for your review by the</p>	<p>1 Q. Have you ever seen this chart before?</p> <p>2 A. No.</p> <p>3 Q. Okay. You see where it has type of mesh,</p> <p>4 microporous, medium, and macroporous?</p> <p>5 A. Yes.</p> <p>6 Q. Can we agree microporous means small pore</p> <p>7 and macroporous means large pore?</p> <p>8 A. We can agree on that, yes.</p> <p>9 Q. All right, and, then, you see where it</p> <p>10 says hernia?</p> <p>11 A. Yes.</p> <p>12 Q. And then you see where it EWH&amp;U? Do you</p> <p>13 see that?</p> <p>14 A. Yes.</p> <p>15 Q. Is that abbreviation for Ethicon Women's</p> <p>16 Health?</p> <p>17 A. Yes.</p> <p>18 Q. And if you look at the first page, you'll</p> <p>19 see that this document came out of Ethicon's internal</p> <p>20 files, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Because it bears a Bates stamp number</p> <p>23 from the company, correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And under microporous meshes, does the</p>

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<p>1 document list Prolene as a microporous mesh?</p> <p>2 A. This documents list Prolene as</p> <p>3 microporous.</p> <p>4 Q. And it's not just talking about hernia</p> <p>5 mesh, is it?</p> <p>6 A. No, it does mention TVT slings.</p> <p>7 Q. Okay. That includes TVTO, doesn't it?</p> <p>8 A. It just says TVT slings, in plural.</p> <p>9 Q. Which would include the entire family of</p> <p>10 TVT slings, correct?</p> <p>11 MS. GALLAGHER: Object to form.</p> <p>12 A. I cannot testify to that because there's</p> <p>13 no date on this document and there's no specification</p> <p>14 of TVTO or TVT or any other TVTs.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. Well, because TVTs all use the same mesh,</p> <p>17 do they not?</p> <p>18 A. TVTs use the same, and all the products</p> <p>19 use the same mesh.</p> <p>20 Q. So, when it says TVT slings, that</p> <p>21 includes the entire family of TVTs, right, because they</p> <p>22 all use the same, and have always used the same mesh?</p> <p>23 A. Yes, but all it says is TVT slings.</p> <p>24 Q. Right, and they're talking about the mesh</p> <p>25 being microporous. You see that?</p>	<p>1 A. It used a light, lighter weight, yes.</p> <p>2 Q. And the lighter-weight, large-pore</p> <p>3 Ultrapro mesh has been available to the market since at</p> <p>4 least 2003, has it not?</p> <p>5 A. I don't know exactly when. You're</p> <p>6 talking about the Ultrapro?</p> <p>7 Q. Yes, sir.</p> <p>8 A. No, I don't know when that was available</p> <p>9 on the market.</p> <p>10 Q. You know it was years before 2010,</p> <p>11 though?</p> <p>12 A. No, I do not know that.</p> <p>13 Q. You don't know, you have no clue when</p> <p>14 Ultrapro was put on the market?</p> <p>15 A. No.</p> <p>16 Q. Okay. Do you, you, you've implanted</p> <p>17 Prolift Plus Ms, have you not?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. That's a partially-absorbable</p> <p>20 mesh?</p> <p>21 A. That's a partially-absorbable mesh, yes.</p> <p>22 Q. And you know you were implanting that</p> <p>23 years before 2010, correct?</p> <p>24 A. I did not use Ultrapro.</p> <p>25 Q. Okay. When did you use Ultrapro?</p>
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<p>1 A. Yes.</p> <p>2 Q. And you've never seen this document</p> <p>3 before, have you?</p> <p>4 A. No.</p> <p>5 Q. The lawyers didn't show it to you, did</p> <p>6 they?</p> <p>7 A. I, I just, I just haven't seen it.</p> <p>8 Q. You disagree with that description, I</p> <p>9 gather?</p> <p>10 A. I do.</p> <p>11 Q. Okay. And it says macroporous, and it</p> <p>12 has Vypro, Vypro II, Ultrapro. Do you know what those</p> <p>13 are?</p> <p>14 A. Yes.</p> <p>15 Q. Those are, Ultrapro is the mesh that was</p> <p>16 used in Gynemesh Plus M and Prolift Plus M, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And you're familiar with those products,</p> <p>19 correct?</p> <p>20 A. I am familiar with them.</p> <p>21 Q. You implanted Prolift repeatedly, did you</p> <p>22 not?</p> <p>23 A. I did.</p> <p>24 Q. And that used a lighter-weight,</p> <p>25 large-pore mesh, did it not?</p>	<p>1 A. I used the polyglecaprone polypropylene</p> <p>2 mesh when it became available with Gynemesh. I'm</p> <p>3 sorry, with Prolift Plus M.</p> <p>4 Q. What mesh was Prolift Plus M?</p> <p>5 A. Polyglecaprone polypropylene.</p> <p>6 Q. Okay. That's partially absorbable, is it</p> <p>7 not?</p> <p>8 A. That's partially absorbable.</p> <p>9 Q. It's a lighter-weight mesh, is it not,</p> <p>10 than Prolene?</p> <p>11 A. It's heavier when it's implanted. It</p> <p>12 just gets lighter as the polyglecaprone component is</p> <p>13 absorbed.</p> <p>14 Q. Because it absorbs and becomes a lighter</p> <p>15 mesh, correct?</p> <p>16 A. Yes, it's lighter when you, when you take</p> <p>17 it out, and you measure after the polyglecaprone</p> <p>18 component, it's lighter.</p> <p>19 Q. And the pores on the Ultrapro are</p> <p>20 considerably larger than they are in the Prolene, are</p> <p>21 they not?</p> <p>22 A. I don't know exactly in the product of</p> <p>23 Ultrapro, and I don't want to infer from one product to</p> <p>24 another on these, on these devices.</p> <p>25 Q. You've implanted all of them, Prolifts,</p>

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<p>1 TVT slings, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you know that they have considerably</p> <p>4 larger pores in the Ultrapro than the TVT Prolift.</p> <p>5 A. You're asking about Ultrapro, but if you</p> <p>6 ask me about Prolift Plus M, we'll have a better</p> <p>7 understanding of it. I just don't want to give</p> <p>8 testimony on Ultrapro that is used for hernia.</p> <p>9 Q. Okay. I see the distinction. Let me</p> <p>10 clear it up. You know that Ultrapro mesh is used in</p> <p>11 Prolift Plus M?</p> <p>12 A. It is polyglecaprone polypropylene, yes.</p> <p>13 Q. And you've used it?</p> <p>14 A. I have used it, yes.</p> <p>15 Q. And it has considerably larger pores than</p> <p>16 Prolene mesh, correct?</p> <p>17 A. It has a larger pore than Prolene mesh,</p> <p>18 yes.</p> <p>19 Q. And all of these products that are being</p> <p>20 discussed here, these are either pelvic floor prolapse</p> <p>21 products or stress urinary incontinence products,</p> <p>22 correct?</p> <p>23 A. Well, Gynemesh Plus M and Prolift Plus M</p> <p>24 are for prolapse. TVT slings are for incontinence.</p> <p>25 Q. And Prosima is for prolapse, correct?</p>	<p>1 A. Yeah, the, the reports for -- the</p> <p>2 definitions for microporous and macroporous are very</p> <p>3 clear.</p> <p>4 Q. Now, do you know Joerg Holste?</p> <p>5 A. No.</p> <p>6 Q. Have you ever heard of him before?</p> <p>7 A. No.</p> <p>8 Q. I'm the first, me uttering his name is</p> <p>9 the first time you ever heard it?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 A. I may have heard his name from, or seen</p> <p>13 it, but I don't, maybe once, I don't know, I don't</p> <p>14 recall this, this person.</p> <p>15 Q. Okay, did you know that you put down on</p> <p>16 your reliance list that you read his deposition and</p> <p>17 relied on it in forming your report in this case?</p> <p>18 A. I read that over a year, a year ago, yes.</p> <p>19 Q. Well, you just signed this last week,</p> <p>20 didn't you, sir?</p> <p>21 A. Well, you just asked me if I knew him. I</p> <p>22 don't know him.</p> <p>23 Q. I asked you do you know who he is. You</p> <p>24 don't even know who he is?</p> <p>25 A. I don't know who he is.</p>
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<p>1 A. Prosima is for prolapse as well as</p> <p>2 Prolene and Gynemesh.</p> <p>3 Q. That's what I'm saying, every one of the</p> <p>4 products listed on this exhibit are products for the</p> <p>5 treatment of either pelvic organ prolapse or stress</p> <p>6 urinary incontinence, correct?</p> <p>7 A. On the column, on the side, under EWH&amp;U,</p> <p>8 yes.</p> <p>9 Q. And you would disagree with that</p> <p>10 document?</p> <p>11 A. On what part would I disagree?</p> <p>12 Q. That, describing TVT slings as being</p> <p>13 microporous?</p> <p>14 A. Yeah, I do disagree with that.</p> <p>15 Q. Do you agree that Gynemesh Plus M and</p> <p>16 Prolift Plus M is macroporous, do you agree with that</p> <p>17 portion?</p> <p>18 A. They're all macroporous.</p> <p>19 Q. You would put every one of these products</p> <p>20 in the macroporous category, not the three separate</p> <p>21 categories that Ethicon internally did, correct?</p> <p>22 A. Yes, that's, they're all macroporous</p> <p>23 products.</p> <p>24 Q. Even if Ethicon describes them as three</p> <p>25 different weights?</p>	<p>1 Q. Okay, that's fine. And three days ago</p> <p>2 you supplemented your reliance list, and Dr. Holste is</p> <p>3 listed as one of the depositions you read and relied on</p> <p>4 in forming your opinions, correct?</p> <p>5 A. Yeah, I read it a very long time ago.</p> <p>6 Q. Okay. But he's on your reliance list,</p> <p>7 correct?</p> <p>8 A. He's on my reliance list, yes.</p> <p>9 (Plaintiff's Exhibit No. 12 was marked</p> <p>10 for identification.)</p> <p>11 BY MR. FREESE:</p> <p>12 Q. Let me show you Exhibit 12 to your</p> <p>13 deposition, sir, and show you a question and answer</p> <p>14 that Dr. Holste was asked at his deposition, the</p> <p>15 deposition that you got on your reliance list. He</p> <p>16 says, the question is, quote, "And Prolene</p> <p>17 old-construction mesh at 100 to 110 grams per meter</p> <p>18 squared is considered a heavyweight mesh, correct?"</p> <p>19 Answer: "Correct."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. And you disagree with Dr. Holste?</p> <p>23 A. No, 110 grams per square meter, that's</p> <p>24 heavy.</p> <p>25 Q. That's a heavyweight?</p>

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<p>1 A. That's the heaviest I've ever seen, by 2 the way. 3 Q. Did you know that Prolene was 100 to 110 4 grams per meter squared? Did you know that was the 5 weight of Prolene? 6 A. No, that's old-construction Prolene. 7 Q. That's old-construction Prolene. Do you 8 know that's the same mesh that TVTs are made out of? 9 A. No, I don't know that. 10 Q. Okay, you don't believe that? 11 A. I don't believe that. 12 Q. Okay. But you would agree that if the 13 mesh is 100 to 110 grams per meter squared, that's a 14 heavyweight mesh under anybody's definition, correct? 15 A. That's the heaviest I've ever seen. 16 Q. Okay. And you think that's a different 17 mesh than what's used in TVT? 18 A. Yes. 19 Q. And you've never seen, that you recall, 20 this deposition testimony I just showed you, right? 21 MS. GALLAGHER: Object to form. 22 A. I, I read about his deposition, I read 23 his, may have read his deposition once. 24 BY MR. FREESE: 25 Q. Which you said you relied on in your</p>	<p>1 Q. Now, do you know who Brigitte Hellhammer 2 is? 3 A. No. 4 Q. Have you ever heard that name before? 5 A. I don't recall that one. 6 (Plaintiff's Exhibit No. 14 was marked 7 for identification.) 8 BY MR. FREESE: 9 Q. All right. Let me show you what I've 10 marked as Exhibit 14 to your deposition, sir. 11 MS. GALLAGHER: Did we skip 13? 12 MR. FREESE: I did. I'm going to come 13 back to 13. 14 BY MR. FREESE: 15 Q. You see Dr. Hellhammer here? Do you see 16 that, sir? 17 A. Okay, yeah, I see her name here. 18 Brigitte Hellhammer. 19 Q. And you testified that Prolene was, was a 20 large-pore mesh, correct? 21 A. Yes. 22 Q. All right. And you see that in 23 September, 2013, Dr. Hellhammer's deposition was taken, 24 just like we're here taking yours, and she's under 25 oath, and she was asked the question: "And you agree</p>
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<p>1 reliance materials, correct? 2 A. Right. 3 Q. This is the guy who you said you relied 4 on, correct? 5 A. No, this is the guy that you're showing 6 me a picture right now that you tell me that I have 7 relied on. 8 Q. No, sir, I'm showing you your reliance 9 list. Joerg Holste. You see that? Here's a nice 10 picture of Dr. Holste. Deposition testimony of Dr. 11 Holste taken July 29th, 2013. Do you see that? 12 A. Yes. 13 Q. Same guy, right? 14 A. Yes. 15 Q. Okay. 16 A. I don't know if that's the same guy. 17 Q. Well, if it's not, I'm sure Ms. Gallagher 18 is going to let me know very quickly, but if that's the 19 same guy, we can at least agree that you don't agree 20 with Dr. Holste saying that Prolene mesh is 21 heavyweight, but you agree that at 110 grams per meter 22 squared is heavyweight mesh? 23 MS. GALLAGHER: Object to form. 24 A. Yes, that's the heaviest I've ever seen. 25 BY MR. FREESE:</p>	<p>1 that Prolene mesh that was used in TVT was small-pore 2 mesh, correct?" And what was her answer, sir? 3 A. She answered yes. 4 Q. And do you recall ever seeing this 5 deposition question and answer before today? 6 A. No. No, I certainly do not recall this 7 one specifically. 8 Q. Do you realize that she also appears on 9 your reliance list? 10 A. Yes. 11 Q. That you relied specifically on her 12 deposition that was taken on 9/11 and 9/12 of 2013. Do 13 you see that? 14 A. Oh, she's in the whole list of those 15 documents. I did not, I do not rely for my opinion on 16 whatever she says. 17 Q. I'm not asking you that, sir. I'm asking 18 you, you put on your reliance list that you read and 19 relied on Dr. Hellhammer, and I've just shown you a 20 question and answer where she said Prolene mesh was a 21 small-pore mesh. Do you see that? 22 MS. GALLAGHER: Object to form. 23 A. But I disagree with her. 24 BY MR. FREESE: 25 Q. I understand that. That was my next</p>

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<p>1 question. You disagree with her, correct?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Do you know who she is?</p> <p>4 A. No.</p> <p>5 Q. Do you know what her background is?</p> <p>6 A. No.</p> <p>7 Q. Do you know whether or not you're more</p> <p>8 familiar with the pore size of mesh than Dr. Hellhammer</p> <p>9 is?</p> <p>10 A. I know what I know. I don't know what</p> <p>11 she knows.</p> <p>12 Q. Do you know she's a German employee of</p> <p>13 Ethicon?</p> <p>14 A. No.</p> <p>15 Q. Did you know that Dr. Holste was a</p> <p>16 materials expert for Ethicon in Germany?</p> <p>17 A. No, I don't, I don't know that.</p> <p>18 Q. And you simply disagree with her</p> <p>19 conclusion, is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. All right. Now, let me show you what I'm</p> <p>22 marking as Exhibit 13 to your deposition.</p> <p>23 (Plaintiff's Exhibit No. 13 was marked</p> <p>24 for identification.)</p> <p>25 BY MR. FREESE:</p>	<p>1 A. Yes.</p> <p>2 Q. That's heavyweight mesh, is it not?</p> <p>3 A. That is a heavyweight, yes.</p> <p>4 Q. And you just described, you told me</p> <p>5 anything that would be 105 to 110 grams would be the</p> <p>6 heaviest mesh you can recall, correct?</p> <p>7 A. A hundred ten is the largest that I have</p> <p>8 seen.</p> <p>9 Q. And if we look at Prolene mesh, that is</p> <p>10 the mesh used in TVT, is it not?</p> <p>11 A. The Prolene mesh are used on TVT may be</p> <p>12 lower than that.</p> <p>13 Q. Well, do you have anything that says it</p> <p>14 is?</p> <p>15 A. Yes, actually, yes, I think I have a</p> <p>16 paper that actually says that.</p> <p>17 Q. Well, I'm showing you a paper that you</p> <p>18 relied on to put in your, your reliance list that says</p> <p>19 the weight of the Prolene mesh is 105 grams per meter</p> <p>20 squared. You have no reason to dispute that, do you?</p> <p>21 A. Yeah, but this is a, this is a paper</p> <p>22 about hernia.</p> <p>23 Q. It's dealing with Prolene mesh, sir. You</p> <p>24 understand that, do you not?</p> <p>25 A. Yeah, I do understand that.</p>
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<p>1 Q. I think we went backwards. But, you see</p> <p>2 this article, sir?</p> <p>3 A. Yes.</p> <p>4 Q. The argument for lightweight</p> <p>5 polypropylene mesh in hernia repair?</p> <p>6 A. I see this article, yes.</p> <p>7 Q. By Dr. Cobb and Dr. Kercher and Dr.</p> <p>8 Heniford?</p> <p>9 A. Yes.</p> <p>10 Q. Have you seen this article before, sir?</p> <p>11 A. I may have seen it. I can not remember.</p> <p>12 Q. Did you realize it's on your reliance</p> <p>13 list?</p> <p>14 A. It's probably on my reliance list, yes.</p> <p>15 Q. Okay. And did you read it?</p> <p>16 A. Yes, actually, I read that sometime ago,</p> <p>17 even before it was, it was a matter of litigation.</p> <p>18 Q. Okay, turn to the second page. It says</p> <p>19 concept of lightweight mesh. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And you see that there's a table of</p> <p>22 polypropylene meshes with different densities?</p> <p>23 A. Yes.</p> <p>24 Q. And you see that Dr. Cobb has reported</p> <p>25 that Prolene mesh is 105 grams per meter squared?</p>	<p>1 Q. And it's reporting Prolene mesh at 105</p> <p>2 grams per meter squared, correct?</p> <p>3 A. Yes, it is reporting that.</p> <p>4 Q. And you said it's dealing with hernia,</p> <p>5 but you cited it yourself in your own report, did you</p> <p>6 not?</p> <p>7 A. It's not specifically for this hernias.</p> <p>8 I do not cite in this report for Jennifer Ramirez, I do</p> <p>9 not cite this specific report.</p> <p>10 Q. Yes, you did. You don't think that you</p> <p>11 cited this article in your report?</p> <p>12 A. Yeah, I want to see exactly where, where</p> <p>13 is it.</p> <p>14 Q. I'm talking about in your reliance list.</p> <p>15 A. Oh, okay, you're talking about reliance</p> <p>16 list, yes, it is in the reliance list.</p> <p>17 Q. Okay, because you've given us a 100-page</p> <p>18 reliance list that says these are the materials that</p> <p>19 Jaime Sepulveda has relied on in forming my opinions,</p> <p>20 correct?</p> <p>21 A. Yes, but --</p> <p>22 MS. GALLAGHER: Form.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. And that includes this article, does it</p> <p>25 not?</p>

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<p>1 A. Yes, but the definition of relied doesn't</p> <p>2 mean that I'm using it for my, for my, to, to</p> <p>3 substantiate my, my opinion. I, I do read papers that</p> <p>4 I exclude as I, as I'm reading them.</p> <p>5 Q. You didn't exclude this paper from your</p> <p>6 reliance list, did you? You included it.</p> <p>7 A. Yes, it's included in there, but it's not</p> <p>8 in my report.</p> <p>9 Q. And, in fact, Prolene mesh is even</p> <p>10 heavier than Marlex, is it not?</p> <p>11 A. Yes, it shows that.</p> <p>12 Q. And you know what Marlex is, do you not?</p> <p>13 A. I know Marlex, yes.</p> <p>14 Q. It's polypropylene also, is it not?</p> <p>15 A. Yes, but it's not a multifilament.</p> <p>16 Q. You think Marlex is a multifilament?</p> <p>17 A. Yes, it's just a multifilament.</p> <p>18 Q. Okay, and what product is Marlex used in?</p> <p>19 A. The pore size is a lot smaller because</p> <p>20 it's a multifilament.</p> <p>21 Q. Okay, where did you get that from?</p> <p>22 A. From what I have read.</p> <p>23 Q. Okay, can you cite me any --</p> <p>24 A. That's Mersilene.</p> <p>25 Q. You think Marlex is Mersilene?</p>	<p>1 Q. And that is about one-quarter the weight</p> <p>2 of Prolene, is that correct?</p> <p>3 A. That's about a quarter, yes, according to</p> <p>4 this table, yes.</p> <p>5 Q. Now, Doctor, would you look at, down at</p> <p>6 the first column on the concept of lightweight mesh,</p> <p>7 you see it there?</p> <p>8 A. Yes.</p> <p>9 Q. See where it says Marlex?</p> <p>10 A. Yes.</p> <p>11 Q. Marlex, paren, C.R. Bard. Do you know</p> <p>12 who C.R. Bard is?</p> <p>13 A. That's a company, yes.</p> <p>14 Q. That makes slings, correct?</p> <p>15 A. They, they do make slings.</p> <p>16 Q. It says Marlex is a standard monofilament</p> <p>17 heavyweight polypropylene mesh. Do you see that?</p> <p>18 A. Is a monofilament, yes.</p> <p>19 Q. So, you want to retract your last answer</p> <p>20 about Marlex?</p> <p>21 A. No, because it's a, with the pore size</p> <p>22 that it has, it's a, that's a multifilament.</p> <p>23 Q. Well, according to the Cobb article, it's</p> <p>24 a standard monofilament. Do you disagree, then, that</p> <p>25 Marlex is a standard monofilament heavyweight</p>
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<p>1 A. Yes.</p> <p>2 Q. Okay. Marlex is polypropylene, Dr.</p> <p>3 Sepulveda.</p> <p>4 A. Yes, so, it's a Mersilene.</p> <p>5 Q. And you think that, that Marlex is a</p> <p>6 multifilament?</p> <p>7 A. Yes.</p> <p>8 Q. And what is your support for that?</p> <p>9 A. That I have read about Marlex before.</p> <p>10 Q. Okay. Do you know that it's used in, in</p> <p>11 Boston Scientific and AMS slings?</p> <p>12 A. I never used a Boston Scientific.</p> <p>13 Q. You've used AMS slings before, have you</p> <p>14 not?</p> <p>15 A. I used AMS slings, but they were not made</p> <p>16 of Marlex.</p> <p>17 Q. Okay. Who do you think makes the</p> <p>18 polypropylene for AMS and Bard and Boston Scientific</p> <p>19 slings?</p> <p>20 A. I don't know.</p> <p>21 Q. You don't think it's Marlex, though?</p> <p>22 A. No, it's not Marlex.</p> <p>23 Q. And you see where it says the weight of</p> <p>24 Ultrapro is 28 grams per meter squared?</p> <p>25 A. Yes.</p>	<p>1 polypropylene mesh?</p> <p>2 A. Yes, the pore size in Marlex is a small,</p> <p>3 is a small size and it behaves like a multifilament.</p> <p>4 The weave, the weave -- I'm sorry, the knit is a</p> <p>5 multifilament.</p> <p>6 Q. This article says it's a monofilament,</p> <p>7 not a multifilament. Do you see that?</p> <p>8 A. That's what this article says.</p> <p>9 Q. And you disagree with the Cobb article on</p> <p>10 that?</p> <p>11 A. Yes, the fibers are too close.</p> <p>12 Q. It goes on to say that it contains 95</p> <p>13 grams per meter squared of polypropylene, is porous but</p> <p>14 has very small inter -- I always have a hard time</p> <p>15 pronouncing that.</p> <p>16 A. Interstices.</p> <p>17 Q. Would you tell us what that is, please?</p> <p>18 A. It's the space in between the fibers.</p> <p>19 Q. It says it's extremely strong. It says</p> <p>20 several comparable formulations of heavyweight</p> <p>21 polypropylene are available with a similar</p> <p>22 polypropylene content as Marlex, including Prolene,</p> <p>23 Ethicon, Inc., Somerville, New Jersey. Do you see</p> <p>24 that?</p> <p>25 A. Yes, that's what it says, yes.</p>

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<p>1 Q. That's saying that, that from a weight 2 standpoint, that Prolene and Marlex are both 3 monofilament heavyweight meshes, correct? 4 A. Marlex is lighter, but the configuration 5 of Marlex makes it as a multifilament. 6 Q. That's not my question. According to Dr. 7 Cobb, both Prolene and Marlex are heavyweight 8 polypropylene meshes, correct? 9 A. According to, to Dr. Cobb, it's, it's 10 porous but has very small interstices, which is what 11 I've been referring to. 12 Q. And it says several comparable 13 formulations of heavyweight polypropylene are available 14 with similar polypropylene content as Marlex, including 15 Prolene, correct? 16 A. Yes, including Prolene. 17 Q. Do you agree or disagree with that 18 statement? 19 A. Well, it says that there are several, 20 several heavyweights. That's what he is explaining. 21 Q. He says Marlex and Prolene are both 22 heavyweight polypropylene mesh. 23 A. That's what he says, that it's 24 heavyweight, yes. 25 Q. And you disagree with that?</p>	<p>1 Q. Okay, you're saying the use of the 2 plastic sheath reduces the deformation of the mesh when 3 it's being implanted? 4 A. Yes, and the, when the IFU explains that 5 there is, not to put it too tight, that's how you 6 prevent deformation. 7 Q. Deformation of the, of the mesh is an 8 unwanted result, is it not? 9 A. No, when I talk about deformation, I'm 10 talking about biomechanical deformation. Deformation 11 in biomechanics is different from deformation that we 12 see normally, and deformation has to do with the change 13 on the dimensions of the tape. 14 Q. I'm not, I'm not quibbling with you about 15 that, but we can agree that deformation generally is an 16 unwanted result of the mesh, either mechanically or in 17 vivo, or any process you don't want the mesh to deform, 18 correct? 19 A. Well, in any viscoelastic that is used 20 will have a degree of deformation, which is that it 21 changes in shape. Any, any viscoelastic, any 22 viscoelastic substance will go through deformation, 23 your skin, your ligaments, and any implant that you may 24 place. 25 Q. Look at page 19, sir. The last</p>
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<p>1 A. Yeah, the, the mesh in use of slings is 2 not a heavyweight mesh. 3 Q. Well, if it's 105 grams per meter 4 squared, you would agree that it's heavyweight, right? 5 A. Yes, that's heavy. 6 Q. All right, and if I proved to you at 7 trial that Prolene mesh used in TVT and TVTO and TVT 8 Abbrevio and TVT Secur is 105 grams per meter squared, 9 we would all agree then that that's heavyweight mesh? 10 A. At 105 or 110, what I have shown you, you 11 have shown me, I will have no other choice but to agree 12 with you. 13 Q. Thank you, sir. Dr. Sepulveda, if you 14 would look at page 18 of your report. You see where, 15 in the first full paragraph, you say, when placed per 16 the IFU, the risk of deformation of the tape is 17 reduced? 18 A. When placed per the IFU, the risk of 19 deformation of the tape is reduced. 20 Q. You see that? 21 A. Yes. 22 Q. And my only question is, is reduced 23 compared to what? 24 A. It's to, to the deformation that you 25 would have if you put it without plastic sheaths.</p>	<p>1 paragraph, where it starts with complications. 2 A. Yes. 3 Q. You see where it says the transobuturator 4 approach showed a higher frequency of early 5 postoperative pain as the insertion needle went through 6 the superficial muscles of the leg? Do you see that? 7 A. Yes. 8 Q. What are you defining as superficial 9 muscles of the leg? 10 A. Specifically, the adductor magnus. 11 Q. The adductor magnus muscles? 12 A. Yes. 13 Q. Okay. And you go on, this complication 14 is most often transient and managed with medication. 15 What does it mean, most often transient? 16 A. It's of short duration. 17 Q. Okay. So, more than half the time it's 18 of short duration? 19 A. Yes. 20 Q. All right, and it could also be a 21 long-term pain and a long-term complication, can it 22 not? 23 A. I think that was defined as something 24 that is extremely rare. 25 Q. And how do you define extremely rare?</p>

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<p>1 A. It's when, when you look at the, at the 2 leg pain in the cohorts that are five years and seven 3 years, there's, there's a very low rate of long-term 4 pain. Actually, it's not, it's not described in many 5 of these papers, it's not described. 6 Q. Look on page 20. You see the paragraph 7 that begins it became evident that specialized 8 knowledge of the obturator site and the anatomy and 9 relationship of the vascular, muscular and nerve 10 studies were required for a reproducible and safe 11 obturator procedure, do you see that? 12 A. Yes. 13 Q. Where is that in the IFU? Where does it 14 say that, that you need special knowledge of the 15 anatomy in order to safely implant an obturator device? 16 A. It's part, knowing the anatomy is part of 17 what is required from a physician as stated on the IFU. 18 It's physicians that are familiarized with continence 19 procedures. 20 Q. But you're saying specialized knowledge 21 over and above the average physician is necessary? 22 A. No, specialized knowledge is knowing 23 exactly about the obturator space. 24 Q. But specialized knowledge compared to 25 who?</p>	<p>1 bundle. 2 Q. How far is a properly-placed TVTO from a 3 pudendal nerve bundle? 4 A. It's at least four centimeters. 5 Q. You go on to say, on the next page, the 6 proximity to the obturator neurovascular bundle was 7 most frequently a failure to orient the device from 45 8 degrees to 90 degrees as specified by the IFU. 9 A. Yeah, there are three, three factors that 10 have been validated as the variations in the placement 11 of a transobturator sling from the inside out. The 12 first factor is the dorsal lithotomy position, which is 13 addressed by the IFU. The second factor is the 14 insertion, or the depth of the insertion of the needle 15 in the periurethral space, and the, the third factor is 16 a full rotation of the wrist with rotation from 45 to 17 90 degrees when the needle is exteriorized. Those 18 three factors determine how close the tape is going to, 19 is going to be in relation to the neurovascular bundle. 20 Q. All right, and if it's not done that way, 21 then you can get an obturator nerve injury? 22 A. Yes, if you, if you actually dissect a 23 cadaver and you insert it wrong to see where you get 24 out, you can, you can get there. 25 Q. You say you can get there, you can get</p>
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<p>1 A. Compared to what you do normally. I'm 2 going to explain that. 3 Q. What I want to know is, are you talking 4 about special knowledge within a subgroup of doctors, 5 or simply you have to have more anatomical knowledge 6 than, say, a court reporter or a lawyer? 7 A. No, you, you need, even if do you 8 continence procedures, you're going to, you're needing 9 to know the anatomy of the obturator space. 10 Q. Is it anywhere in the IFU that you have 11 to have specialized knowledge of the anatomy in order 12 to safely reproduce an obturator procedure? 13 A. It just says that physicians should be 14 trained on the procedure. 15 Q. Okay. And it says that the, the, the 16 obturator neurovascular bundle 1.2 to 1.5 centimeters 17 for TVTO, that's the distance between where a 18 properly-placed TVTO should go in the obturator nerves? 19 A. That's what has been, has been measured. 20 Q. Okay. So, in other words, if a TVTO is 21 properly placed, it should be 1.2 to 1.5 centimeters 22 from the obturator nerve bundle? 23 A. Yes, there's a safe area for placement of 24 a transobturator sling that is about 2.5 centimeters, 25 1.5 to 2.5 centimeters from the obturator neurovascular</p>	<p>1 there and you can damage or injure an obturator nerve? 2 A. You can, you can injure an obturator 3 nerve as has been shown in some, some reports. 4 Q. Now, Doctor, you discussed -- 5 A. And when I say as it has been shown in 6 some reports is that anatomically, it has been 7 described that when you don't insert the device 8 properly, you can injure the neurovascular bundle. 9 Q. All right. Have you ever seen a report 10 of an obturator nerve injury from the explant of a TVT? 11 A. No. 12 Q. As you sit here today, there's no 13 literature that we can find that, that you've seen 14 that's been reported where any patient has suffered an 15 obturator nerve injury from the revision or removal of 16 a mesh sling? 17 A. No, I have not seen an obturator nerve 18 injury from the removal of a, a sling. 19 Q. And what about the pudendal nerve injury, 20 have you ever seen a report of a patient getting a 21 pudendal nerve injury from the removal or revision of a 22 sling? 23 A. I have not seen that, that report. 24 Q. Ever? 25 A. It has not been published.</p>

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<p>1 Q. Have you in your practice come across</p> <p>2 that?</p> <p>3 A. No, I have not seen that in my practice.</p> <p>4 Q. You say in 2013 that the -- well, strike</p> <p>5 that.</p> <p>6 You document 2008, 2011, 2013 FDA Public</p> <p>7 Health Notifications regarding synthetic mesh?</p> <p>8 A. Well, for this one it's the 2008 because</p> <p>9 the sling wasn't implanted in 2010 in this case.</p> <p>10 Q. Right. So, the only, the only FDA notice</p> <p>11 that Dr. Reyes could have been aware of is the 2008,</p> <p>12 correct?</p> <p>13 A. That is correct.</p> <p>14 Q. Because the 2011, 2013, hadn't even come</p> <p>15 out yet?</p> <p>16 A. That's correct.</p> <p>17 Q. All right. Doctor, you say on page 22 of</p> <p>18 your report that the TVTO device is accompanied by an</p> <p>19 IFU and that you have reviewed the TVTO IFU. Correct?</p> <p>20 A. Please repeat that.</p> <p>21 Q. Yeah, I was reading that you have</p> <p>22 reviewed the TVTO IFU and you find it adequate and</p> <p>23 complete for its use in the operating room?</p> <p>24 A. Yes, I did.</p> <p>25 Q. And you said I understand that the IFU is</p>	<p>1 the known risks and adverse events in the IFU so that</p> <p>2 information will be available to the doctor to pass on</p> <p>3 to patient, do you agree with that?</p> <p>4 A. I expect Ethicon to state the risks</p> <p>5 inherently associated to the mesh.</p> <p>6 Q. And do you agree with me that if Ethicon</p> <p>7 fails to provide the necessary information regarding</p> <p>8 the risks and adverse events and complications to the</p> <p>9 doctor, there's a risk at that point that the patient</p> <p>10 cannot be properly counseled because the information</p> <p>11 has not been provided to the doctor, do you agree with</p> <p>12 that statement?</p> <p>13 A. The IFU is intended to educate the</p> <p>14 physician on the performance of the procedure. Part of</p> <p>15 it is going to be the complications from the device</p> <p>16 that remains on the patient.</p> <p>17 Q. Listen to my question. Do you agree with</p> <p>18 me that if Ethicon fails to provide the necessary</p> <p>19 information regarding the risks and adverse events and</p> <p>20 complications to the doctor, there's a risk at that</p> <p>21 point that the patient cannot be properly counseled?</p> <p>22 MS. GALLAGHER: Object to form.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. Do you agree with that statement or not?</p> <p>25 A. We don't, we don't use the IFU for</p>
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<p>1 not a comprehensive guide for surgical treatment of</p> <p>2 SUI. Do you see that?</p> <p>3 A. Yes, that's the way it's stated.</p> <p>4 Q. Do you agree that a doctor implanting a</p> <p>5 TVTO should be allowed to rely solely upon the IFU to</p> <p>6 ascertain what complications if any may result from the</p> <p>7 use of that device in counseling his patient?</p> <p>8 A. I think that the IFU needs to speak about</p> <p>9 the specifics of the implant, but the continence</p> <p>10 procedure, the risk of the continence procedure</p> <p>11 pertains to the formation and the training of the</p> <p>12 doctor.</p> <p>13 Q. Well, that's not my question. My</p> <p>14 question is, do you agree that a doctor should be able</p> <p>15 to rely solely on the IFU and nothing else in educating</p> <p>16 himself about the complications that could result from</p> <p>17 the use of a device?</p> <p>18 A. No.</p> <p>19 Q. Is that reasonable or not?</p> <p>20 A. No, they should not rely just on the IFU.</p> <p>21 There's a wealth of data out there about the</p> <p>22 indications and the use of the device.</p> <p>23 Q. Do you agree with me that in order for</p> <p>24 Ethicon to do its best to make sure that a patient is</p> <p>25 appropriately counseled, that Ethicon needs to provide</p>	<p>1 patient counseling.</p> <p>2 Q. Well --</p> <p>3 A. So I disagree, I disagree with the</p> <p>4 statement that if it's not placed on the IFU, I expect</p> <p>5 the IFU to address the complications that have to do</p> <p>6 with the tape, it should give me direction on how to</p> <p>7 use the device, but I, I don't expect them to give me</p> <p>8 the benchmark for patient education.</p> <p>9 Q. And, Doctor, that question didn't involve</p> <p>10 the IFU.</p> <p>11 A. Okay.</p> <p>12 Q. So, you have to listen to my question.</p> <p>13 I'm just asking you if you agree with this statement,</p> <p>14 that if Ethicon fails to provide the necessary</p> <p>15 information regarding the risks and adverse events of</p> <p>16 complications to a doctor, there's a risk at that point</p> <p>17 that the patient cannot be properly counseled because</p> <p>18 the information has not been provided to the doctor.</p> <p>19 Do you agree with that?</p> <p>20 MS. GALLAGHER: Object to form.</p> <p>21 A. No, I disagrees with that because the</p> <p>22 only source of information for a physician before they</p> <p>23 counsel a patient is not Ethicon.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. And do you agree or disagree that if</p>

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<p>1 Ethicon fails, if it happens that Ethicon fails to 2 provide material information about the risks of, for 3 example, a TVT or any medical device, to the physician, 4 if it actually happens and the doctor just relies on 5 the IFU regarding the risks and doesn't tell a patient 6 a risk that the doctor wasn't told about, the patient 7 would not have been properly counseled? 8 MS. GALLAGHER: Object to form. 9 BY MR. FREESE: 10 Q. Do you agree or disagree with that? 11 A. I agree that if the doctor relies just on 12 the IFU, they will not be able to provide enough 13 counseling to the patient. 14 Q. Do you know Dr. Hinoul? 15 A. Yes. 16 Q. He's a medical affairs director at 17 Ethicon, is he not? 18 A. Yes. 19 Q. He's a urogynecologist, is he not? 20 A. He is. 21 Q. He's trained the same way you're trained, 22 correct? 23 A. I don't know if it was the same way, but 24 I know he's a urogynecologist. 25 Q. And his job is to make sure that, from a</p>	<p>1 medical director for Ethicon. 2 Q. Yes. 3 A. So, so, the question is, is that the only 4 thing the doctor relies on, do I agree to that? 5 Q. No, I'm asking do you agree with Dr. 6 Hinoul's answer, absolutely, to the question that was 7 just asked; do you agree with his answer? 8 A. Yeah. In order for Ethicon to do its 9 best to make sure that a patient is properly counseled, 10 Ethicon needs to provide the known risks and events in 11 the IFU so that information will be available to a 12 doctor to pass on to the patient. Yes, that's -- 13 Q. You agree with that? 14 A. If they're aware, if they're aware of any 15 complications, that will be, that's, Ethicon will have 16 to transmit it for the doctor to be aware. 17 Q. If Ethicon is aware of a complication, 18 they have to transmit it to the doctor? 19 MS. GALLAGHER: Object to form. 20 A. I would agree that that's the only way 21 that the doctor could know. 22 BY MR. FREESE: 23 Q. All right. Okay. And, he goes on to 24 say, "And, therefore, if Ethicon fails to provide the 25 necessary information regarding risks and adverse</p>
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<p>1 medical standpoint, that doctors are getting properly 2 warned of the risks of using TVT, correct? 3 MS. GALLAGHER: Object to form. 4 A. I'm not aware of his job description. 5 BY MR. FREESE: 6 Q. When is the last time you talked to him? 7 A. At an AUGS meeting. 8 Q. Okay. You actually reviewed and logged 9 his deposition in this case, did you not? 10 A. Yes, I did see one of his depositions. 11 Q. I want to show you page 2007 and 2008 of 12 his deposition that was given January 14th, 2014, okay? 13 And you see where it says, quote, "In order for Ethicon 14 to do its best to make sure that a patient is 15 appropriately counseled, Ethicon needs to provide the 16 known risks and adverse events in the IFU so that 17 information will be available to the doctor to pass on 18 to the patient. Right?" And he says, "Absolutely." 19 Do you see that? 20 A. Yes. 21 Q. Do you agree with his answer? 22 A. If Ethicon is the only source, but I 23 think in the context in which he was asked, from what I 24 see from that answer, absolutely, is, is Ethicon going 25 to provide that information, and he's testifying as a</p>	<p>1 events and complications to the doctor, there's a risk 2 at that point that the patient cannot be properly 3 counseled because the information has not been provided 4 to the doctor, correct?" And Dr. Hinoul's answer is, 5 "That is correct." Do you see that? 6 A. Yes, but I disagree with him because I 7 don't -- 8 Q. So, let me, first of all, did I read the 9 question and answer correctly? 10 A. Yes, sir. 11 Q. Do you agree with Dr. Hinoul? 12 A. No, I don't agree that Ethicon is the 13 only source. In his answer, he's saying that, I mean, 14 there's this long, long question, and then he says he 15 agrees. The substance of it is Ethicon is not the only 16 source that I'm going to consider counseling my 17 patients. 18 Q. It doesn't say only source. It says if 19 Ethicon fails to provide the necessary information 20 regarding risks and adverse events and complications. 21 to the doctor, there's a risk at that point that the 22 patient cannot be properly counseled because the 23 information has not been provided to the doctor, 24 correct? And Dr. Hinoul says that is correct, and you 25 disagree with that?</p>

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<p>1 A. Okay, the specific question there on what 2 can be inferred from the question, so I'm going to 3 answer to you the best, the best way I can answer is, 4 if Ethicon does not disclose it, if there's no 5 disclosure, there's no way for the physician to know it 6 unless it has to do with the procedure itself. Now, we 7 don't rely just on the IFU and we don't just rely on 8 Ethicon to tell us about the, the procedure. 9 Q. I'm going to get there, Doctor. I just 10 want to know whether or not you agree or disagree with 11 what Dr. Hinoul just said there. 12 MS. GALLAGHER: Objection to form. He's 13 explaining to you why he can't say agree or 14 disagree. 15 MR. FREESE: Well, I'm not sure he is -- 16 MR. GOSS: I think the form is fine. 17 MR. FREESE: Just form, that's all we 18 need. 19 BY MR. FREESE: 20 Q. Do you understand my question, Dr. 21 Sepulveda? I read you the question on lines 1 through 22 7 of page 1208 and the answer on line 8. All I want to 23 know is, do you agree with Dr. Hinoul or do you 24 disagree with Dr. Hinoul? 25 MS. GALLAGHER: Objection to form.</p>	<p>1 A. I would disagree on that, no. 2 Q. Even though Dr. Hinoul says absolutely, a 3 doctor should be able to rely solely on the IFU, you 4 disagree with Dr. Hinoul? 5 MS. GALLAGHER: Object to form. 6 BY MR. FREESE: 7 Q. Correct? 8 A. Yes, I don't think you're going to find 9 any physician that would agree with just relying solely 10 on the IFU. 11 Q. Let me ask you this, Dr. Sepulveda. Who 12 knows more about the complications of Ethicon's 13 products, you or the medical affairs doctor at Ethicon? 14 MS. GALLAGHER: Object to form. 15 A. I think I'm in a privileged position to 16 know what kind of complications patients have when you 17 follow the IFU. 18 BY MR. FREESE: 19 Q. I'm asking you, who knows more about the 20 complications related to TVTs, Dr. Hinoul or you? 21 MS. GALLAGHER: Object to form. 22 A. I do. 23 BY MR. FREESE: 24 Q. Okay. So the jury should conclude that 25 Jaime Sepulveda knows more than the urogynecologist</p>
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<p>1 A. I will have to disagree with that with 2 Dr. Hinoul, because it implies that the only source 3 that you have is Ethicon, and that's not the only 4 source that I have. 5 BY MR. FREESE: 6 Q. And you understand he was speaking on 7 behalf of Ethicon in his deposition? 8 MS. GALLAGHER: Objection to form. 9 A. Yes, he's the medical director for 10 Ethicon. 11 BY MR. FREESE: 12 Q. And the next question, "And, in fact, if 13 Ethicon fails, if it happens that Ethicon fails to 14 provide material information about the risks, for 15 example, of the TVT or any medical device, to the 16 physician, if that actually happens and the doctor just 17 relies on the IFU regarding the risks and doesn't tell 18 the patient the risks that the doctor wasn't told 19 about, the patient would not have been properly 20 counseled, correct?" His answer is, "I am in full 21 agreement, the surgeon should be able to rely solely on 22 the IFU, absolutely." Do you see that? 23 A. For the patient counseling, solely on the 24 IFU? 25 Q. Yes, sir.</p>	<p>1 hired by Ethicon to be its worldwide medical affairs 2 doctor, you know more than he does? 3 MS. GALLAGHER: Object to form. 4 A. Yes, I have implanted more TVTs than he 5 has. 6 BY MR. FREESE: 7 Q. Who has seen more internal documents 8 about the complications of the use of TVT, you or Dr. 9 Hinoul? 10 A. Dr. Hinoul sees more internal documents. 11 Q. It's not your job to write the IFUs for 12 TVT, is it, or TVTO? 13 A. No, it's not, I don't write the IFUs. 14 Q. You understand that all of the warnings 15 and complications that appear in a TVTO IFU are written 16 by the medical affairs people at Ethicon, correct? 17 MS. GALLAGHER: Object to form. 18 A. That's what I would expect to write it, 19 yes. 20 BY MR. FREESE: 21 Q. People like Dr. Hinoul? 22 A. Yes. 23 Q. He's the one in charge of making sure 24 it's accurate and full and gives the doctors all the 25 information they need regarding complications of the</p>

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<p>1 procedure, correct?</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. He writes the IFU.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. And that's his job 24/7, correct?</p> <p>6 MS. GALLAGHER: Object to form.</p> <p>7 A. I don't know if it's 24/7. He writes the</p> <p>8 IFU.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. But that's his job, that's what a medical</p> <p>11 affairs director does, correct?</p> <p>12 A. I'm not familiar with their duties, but I</p> <p>13 think that he has an input on the IFU.</p> <p>14 Q. And yet, you would substitute your</p> <p>15 judgment for his on what a doctor should rely or not</p> <p>16 rely on out of the IFU?</p> <p>17 A. No, I did not testify on that. I said --</p> <p>18 Q. I'm asking you, is it your opinion</p> <p>19 that --</p> <p>20 MS. GALLAGHER: Don't cut him off,</p> <p>21 please.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. Sorry. Go ahead.</p> <p>24 A. What I testified is that I have placed</p> <p>25 more TVTOs, I've done more follow up on these patients</p>	<p>1 A. I can tell you that any of my 2,000</p> <p>2 patients have called him and say, Piet Hinoul, I'm</p> <p>3 doing great.</p> <p>4 Q. Let's do this, Doctor, can you we agree</p> <p>5 you don't know what, you have no personal knowledge of</p> <p>6 what Dr. Hinoul knows or he doesn't know?</p> <p>7 MS. GALLAGHER: Object to form.</p> <p>8 A. No, I already testified, I'm not aware of</p> <p>9 his job description.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. And you have no idea what he knows or</p> <p>12 what he doesn't know, do you?</p> <p>13 A. Actually, I --</p> <p>14 Q. My question is, what personal knowledge</p> <p>15 do you have of what Piet Hinoul knows or doesn't know</p> <p>16 about complications of TVT slings?</p> <p>17 A. I do not know. I just, I do not know</p> <p>18 that. I just --</p> <p>19 Q. And how many --</p> <p>20 MS. GALLAGHER: Please, let him finish</p> <p>21 his answer.</p> <p>22 MR. FREESE: Because he's now off, not</p> <p>23 responding to my question anymore. He's</p> <p>24 answered my question, now he editorializing.</p> <p>25 So, I mean, as long as I can charge the time</p>
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<p>1 than he has. I use the product, I would know about any</p> <p>2 problems it would have. I would not have continued to</p> <p>3 use the polypropylene mesh for midurethral slings to</p> <p>4 this day if I would have seen or I would have had any</p> <p>5 problems.</p> <p>6 MR. FREESE: Move to strike.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. That's not my question, sir. My question</p> <p>9 is simply, Doctor, you would substitute your judgment</p> <p>10 on what an implanting physician should rely on in the</p> <p>11 IFU over Dr. Hinoul's judgment about what a doctor</p> <p>12 should rely on or can rely on from the IFU, correct?</p> <p>13 MS. GALLAGHER: Object to form.</p> <p>14 A. No, Dr. Hinoul does the, he writes the</p> <p>15 IFU. Dr. Hinoul is in a, in a position to see skewed</p> <p>16 data of how the procedure performs, because I can tell</p> <p>17 you that Dr. Hinoul do not get a phone call or a report</p> <p>18 of how many patients have done better and how many</p> <p>19 patients have been improved in their quality of life.</p> <p>20 He gets --</p> <p>21 BY MR. FREESE:</p> <p>22 Q. How do you know that?</p> <p>23 A. He gets a report about complications.</p> <p>24 Q. How do you know that? How do you know</p> <p>25 what he gets?</p>	<p>1 back to you, I don't mind, but he can't sit</p> <p>2 here and read out of a telephone book, either.</p> <p>3 So, if it's not responsive to my question,</p> <p>4 we're wasting time. He's answered my question.</p> <p>5 If you want to ask him a question on redirect,</p> <p>6 that's fine.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. My question to you is you have no clue</p> <p>9 how many slings Dr. Hinoul has implanted, do you?</p> <p>10 A. Yeah, actually, I asked him.</p> <p>11 Q. And what was his answer?</p> <p>12 A. I, I, I probably remember that it was</p> <p>13 none here in the United States.</p> <p>14 Q. I didn't ask you that. How many slings</p> <p>15 has Dr. Hinoul implanted in his life?</p> <p>16 A. I think in my conversation with him at</p> <p>17 some point, I asked him if he could, if he could just</p> <p>18 come to clinical practice on this, on, on, on the</p> <p>19 United States, and he told me no, that he is a medical</p> <p>20 director.</p> <p>21 Q. Dr. Sepulveda, I have no idea what you</p> <p>22 just said. My question is just simply --</p> <p>23 A. I agree that I ramble. I agree with you</p> <p>24 on that.</p> <p>25 Q. Sir, I have a great deal of respect for</p>

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<p>1 you, let's try not to ramble. My question is simply,  2 do you know how many slings Dr. Hinoul has ever  3 implanted in his life?  4 A. No, Mr. Freeese, I don't know how many  5 slings he has implanted.  6 Q. And do you know how many slings he has  7 taken out in his life?  8 A. No.  9 Q. Do you know how many peer-reviewed  10 articles he's written about slings?  11 A. No, I'm only familiar with his articles  12 on the anatomy of TVTO.  13 Q. You know he's written at length on TVT,  14 correct?  15 A. He, for this case, I actually relied on  16 one specific article that he wrote about the anatomy.  17 Q. My question is you understand that Dr.  18 Hinoul is published in peer-review articles, correct,  19 on TVTs?  20 A. Yes.  21 Q. You, sir, have published zero peer-review  22 articles on TVT slings, correct?  23 A. Yes.  24 Q. Okay. And you've done 2 to 3,000 sling  25 procedures, correct?</p>	<p>1 information is based on my, on dissection of multiple  2 specimens, on the communications that I've had with my  3 peers, and on the, on the, on what's published,  4 although it is true that I have not published on TVT, I  5 am in the forefront of providing patient care, so I  6 know how this product performs.  7 MR. FREESE: Move to strike,  8 non-responsive.  9 BY MR. FREESE:  10 Q. Doctor, you have no personal knowledge of  11 how many doctors just like you that Dr. Hinoul talks to  12 every day in his job?  13 A. I don't know who he talks to in his job.  14 Q. He talks to you, right?  15 A. No, we, we don't talk as part of his job.  16 We, the last time we spoke we were sitting on a meeting  17 enjoying the presentations of the scientific meeting.  18 Q. So, you were not talking about business  19 with Ethicon with Dr. Hinoul?  20 A. No, I don't, I don't talk about those  21 things. We have, we have other subjects that we speak  22 about.  23 Q. You understand Dr. Hinoul has access to  24 all the internal information available at Ethicon,  25 correct?</p>
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<p>1 A. Yes.  2 Q. And you've only seen two or three  3 complications in your entire 2 to 3,000?  4 A. Yes.  5 Q. Do you know how many complications Dr.  6 Hinoul has seen?  7 A. In his line of work, probably has seen  8 more than three.  9 Q. And, so, you've seen three out of 3,000,  10 you have no idea how many he's seen, yet you feel  11 comfortable saying you know more about complications  12 from slings and what doctors need to know than he does?  13 A. No, I say I know more about outcomes. I  14 could say, I could say that I know more about outcomes.  15 Q. You know about three complications out of  16 3,000, he may know way more than that. Yet you want to  17 say that your information is superior to his?  18 MS. GALLAGHER: Object to form.  19 BY MR. FREESE:  20 Q. I mean, you realize Dr. Hinoul is  21 responsible --  22 A. I still have to answer your question.  23 Q. I'm sorry. Go ahead.  24 A. My, my information, my information is on  25 the, on the, on my clinical experience and my</p>	<p>1 A. Yes.  2 Q. You do not, do you?  3 A. I do not.  4 Q. In fact, all you have available to you,  5 Dr. Sepulveda, is what the lawyers for Ethicon want to  6 show you, correct?  7 MS. GALLAGHER: Object to form.  8 A. In terms of the company documents, yes.  9 BY MR. FREESE:  10 Q. Okay. So, the company documents, let's  11 define that, company documents about complications and  12 the frequency of complications, those type of documents  13 within Ethicon you don't have access to, do you?  14 A. No, I do not have access to that.  15 Q. Dr. Hinoul does, does he not?  16 A. I think he does.  17 Q. He has to. He's the medical affairs  18 director.  19 A. He's the medical director for Ethicon.  20 Q. Real quick, Dr. Sepulveda, you've never  21 measured the pore size of the TVT sling, have you?  22 A. Yes.  23 Q. Yes, you have never measured it?  24 A. Yes, I have measured it.  25 Q. Okay, when did you measure it?</p>

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<p>1 A. I put it together actually under the</p> <p>2 microscope at the pathology at South Miami Hospital,</p> <p>3 and I look at it and I measure it and then I confirmed</p> <p>4 what it was. Not only that, the pore size, but also</p> <p>5 the pore sizes with, with Prolift Plus M.</p> <p>6 Q. The Ultrapro?</p> <p>7 A. Prolift Plus M.</p> <p>8 Q. Ultrapro?</p> <p>9 A. It could be Ultrapro, but I did not take</p> <p>10 it as Ultrapro.</p> <p>11 Q. Okay. What was the largest dimension of</p> <p>12 the pore?</p> <p>13 A. On which one?</p> <p>14 Q. On Prolene.</p> <p>15 A. On the Prolene used for TVT was 1,200.</p> <p>16 Q. Okay. And what was -- but that's not</p> <p>17 symmetrical, is it?</p> <p>18 A. No, because of the knit, because of the</p> <p>19 way it's knitted, it could be 1,200, but it's never</p> <p>20 less than a thousand on each side.</p> <p>21 Q. It's never less than a thousand and at</p> <p>22 its greater point it's 1,200?</p> <p>23 A. Yes.</p> <p>24 Q. 1,200 microns?</p> <p>25 A. Microns.</p>	<p>1 Q. Let me stop you and do it one at a time,</p> <p>2 okay? What is your basis for saying biomechanically</p> <p>3 they will not operate the same?</p> <p>4 A. Well, they're two different types of</p> <p>5 material.</p> <p>6 Q. Let me ask a better question. Have you</p> <p>7 seen any internal documents from Ethicon saying that</p> <p>8 they will act differently biomechanically?</p> <p>9 A. No, I have not seen any internal</p> <p>10 documents. I have not read any internal documents.</p> <p>11 Q. If there are internal documents that say</p> <p>12 they would behave similarly biomechanically, would you</p> <p>13 have liked to have seen these documents?</p> <p>14 A. Either similarly or separate, but that's</p> <p>15 just the first part of my answer.</p> <p>16 Q. I understand. We're taking them one at a</p> <p>17 time. So you've seen no document that says it would,</p> <p>18 that an Ultrapro TVTO sling would operate differently</p> <p>19 than one made for a POP, correct?</p> <p>20 A. They're two different, those are two</p> <p>21 different applications.</p> <p>22 Q. Okay, and you've never seen a single</p> <p>23 internal document making that comparison, correct?</p> <p>24 A. No, I have not seen that comparison.</p> <p>25 Q. And whether or not Ethicon concluded</p>
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<p>1 Q. And what did you use to measure the</p> <p>2 microns?</p> <p>3 A. There's a little caliber on the</p> <p>4 microscope.</p> <p>5 Q. When did you do this?</p> <p>6 A. Years so.</p> <p>7 Q. Okay. It's not in your report anywhere.</p> <p>8 A. No.</p> <p>9 Q. Okay, why didn't you put it in the</p> <p>10 report?</p> <p>11 A. I didn't think it was relevant because</p> <p>12 the pore size have been well established by other</p> <p>13 publications.</p> <p>14 Q. Did you record this somewhere when you</p> <p>15 did it?</p> <p>16 A. No, I did not record that.</p> <p>17 Q. Why did you measure the pore size?</p> <p>18 A. Because I like to become familiarized</p> <p>19 with what I implant in my patients.</p> <p>20 Q. What is the basis of your opinion that a</p> <p>21 TVTO made out of Ultrapro is not a safer alternative</p> <p>22 than a TVTO made out of Prolene?</p> <p>23 A. There's a few areas on that. Number one</p> <p>24 is biomechanically, the TVT made of Ultrapro will not</p> <p>25 behave in the same way that a TVT made of Prolene.</p>	<p>1 internally that it would be suitable to use Ultrapro in</p> <p>2 a TVTO application?</p> <p>3 MS. GALLAGHER: Object to form.</p> <p>4 A. I have not seen, I have not that on</p> <p>5 internal documents from Ethicon.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. So your opinion is, I'm Dr. Sepulveda and</p> <p>8 because they're two different applications my opinion</p> <p>9 is they would behave differently?</p> <p>10 MS. GALLAGHER: Object to form.</p> <p>11 A. Yes, biomechanically, they would behave</p> <p>12 differently. It's not that they would say that to me.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. And it's so because Jaime Sepulveda says</p> <p>15 it's so.</p> <p>16 A. No, that's not exactly the case. That</p> <p>17 brings me to the --</p> <p>18 Q. Hold on, we'll stay on this for a second.</p> <p>19 What is your basis other than it's my opinion that they</p> <p>20 would behave differently biomechanically?</p> <p>21 A. By my biomechanical knowledge.</p> <p>22 Q. Okay. Have you conducted any</p> <p>23 biomechanical testing of Prolene mesh versus Ultrapro</p> <p>24 mesh?</p> <p>25 A. No, I have not conducted that test.</p>

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<p>1 Q. Okay. All right, what's your second 2 basis for saying that Ultrapro would not be suitable? 3 A. There was, the way they behave, in my, 4 when you're using it in the operating room, the way 5 they handle, they're different. 6 Q. I understand that's your opinion, but 7 you've done no bench testing on that, correct? 8 A. There's no bench testing on it. 9 Q. You've done no tensile testing, correct? 10 A. I have not done any of the bench testing 11 that would be required to make that conclusion. 12 Q. You've done no cadaveric testing on 13 Ultrapro as a sling versus Prolene, correct? 14 A. No, I have not done that test. 15 Q. And have you reviewed any of Ethicon's 16 internal cadaveric testing? 17 A. No. 18 Q. Do you know whether or not actually 19 Ethicon even tested Ultrapro in a sling application in 20 cadavers? 21 A. No, I'm not aware of their testing. 22 Q. So they didn't show you the results of 23 any cadaver testing for the use of Ultrapro as a sling 24 internally, correct? 25 A. I can not say, I can not under oath say</p>	<p>1 form objection? 2 MS. GALLAGHER: No, because you're asking 3 him about -- I thought the question had safety 4 in it and suitability. He's talking about 5 safer alternative design. That's a different 6 analysis. That's my objection. 7 MR. FREESE: Okay. 8 BY MR. FREESE: 9 Q. Let me clarify. You're answering, Dr. 10 Sepulveda, why Ultrapro would not be suitable or a 11 safer alternative than Prolene for use in a sling 12 application, correct? That's what you're answering? 13 A. In the sling application, yes. 14 Q. And you told me biomechanically, you 15 didn't think it would operate the same? 16 A. That's correct. 17 Q. All right, what's your next reason? 18 A. The second is that we already have a 19 device in place that has been tested extensively 20 clinically. So, whatever, whatever evidence is, comes 21 in has to be stronger than the evidence that we have on 22 TVT. 23 Q. All right. Now, the only, you say that 24 there's not demonstrating empirical evidence because 25 you haven't seen any, you don't know if it's been done</p>
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<p>1 that I'm aware of specific testing or, or experiment 2 that has been done. 3 Q. On anything, bench, cadaver, any kind of 4 application? 5 A. No, I'm not aware of that. 6 Q. All right, what was the next reason, 7 other than biomechanical, why you said that Ultrapro 8 would not be suitable as a sling? 9 MS. GALLAGHER: Object to form. 10 A. The next reason is that there have been 11 no clinical studies -- 12 MR. FREESE: Stop for a second. What's 13 the objection? I want to cure it. 14 MS. GALLAGHER: Because it's as a safer 15 alternative design, that's the question you're 16 asking him. 17 MR. FREESE: No, he told me that he had 18 three reasons why Ultrapro would not be 19 suitable as a, to be used as a TVTO. 20 MS. GALLAGHER: As a safer alternative 21 design is what you're questioning him about. 22 That's what he's answering. 23 MR. FREESE: Yes. 24 MS. GALLAGHER: Okay. 25 MR. FREESE: So, will you withdraw your</p>	<p>1 or not, you just haven't seen any, right? 2 A. Yes, there's, there has been no 3 presentations that I heard on conference, there has 4 been no texts that I have read, there has been no 5 scientific randomized control trials, not even a cohort 6 study that shows the use of a hybrid or partially 7 absorbable sling. 8 Q. So, basically, then, that would be just 9 the same as TVTO, wouldn't it? There were no 10 randomized control studies, there were no cohorts, any 11 of that done before TVTO was launched, correct? 12 A. No, that mischaracterizes my testimony on 13 the basis that they're different, they're two different 14 implants. The implant used on TVTO was the same 15 implant that was used on TVT. The implant that would 16 be used on Ultrapro is not the same as the implant that 17 would be used on TVTO. 18 Q. Well, it's the same implant that was used 19 in Prolift, was it not? 20 A. They are different applications. One 21 is -- 22 Q. They're both pelvic surgeries, are they 23 not? 24 A. Well, they're different applications. 25 One is urinary incontinence, the other one is prolapse.</p>

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<p>1 Q. Okay, so, you said that there was no 2 empirical science, and that is because you haven't seen 3 any, you don't know if there is empirical data within 4 Ethicon because you haven't seen that, but you're 5 simply saying you have not seen a published empirical 6 data comparing an Ultrapro as a sling versus a Prolene, 7 correct?</p> <p>8 MS. GALLAGHER: Object to form.</p> <p>9 A. There's no clinical evidence that shows 10 that using a partially-absorbable sling is superior to 11 the sling that we have used.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. Okay, any other reason?</p> <p>14 A. Yeah, the third reason is the consensus 15 from the societies.</p> <p>16 Q. Well, what has the society said about 17 using Ultrapro as a sling?</p> <p>18 A. I trust that the societies will come up 19 with, with recommendations specifically on the use of 20 the established clinical standard for the treatment of 21 incontinence.</p> <p>22 Q. Should I interpret that to mean that the 23 relevant clinical societies have not commented one way 24 or the other about the use of Ultrapro as a sling?</p> <p>25 A. Actually, they have commented that</p>	<p>1 reason against it. It's silent.</p> <p>2 MS. GALLAGHER: Object to form.</p> <p>3 A. They have no evidence to speak one way or 4 the other.</p> <p>5 The fourth reason is that the FDA, the 6 panel on the FDA on the executive summary did not offer 7 that even as an alternative.</p> <p>8 MS. GALLAGHER: We have lunch. Do you 9 want to break?</p> <p>10 MR. FREESE: Sure.</p> <p>11 (A lunch break was taken from 1:17 p.m. 12 to 1:29 p.m.)</p> <p>13 BY MR. FREESE:</p> <p>14 Q. Dr. Sepulveda, I want you to turn to the 15 Roman numeral IV, expert opinion overview in your 16 report. I think it may be 55 on your version. It's 17 page 54 on mine, I think that's just because of the way 18 it's printed. Tell me when you get there.</p> <p>19 A. Yeah, I'm here.</p> <p>20 Q. Just so I understand, you give opinions 21 throughout your report, but is section IV intended to 22 sort of like summarize the important opinions that you 23 intend to give in a case?</p> <p>24 A. Yes.</p> <p>25 Q. Okay, I realize you give more than what's</p>
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<p>1 specifically the use of monofilament polypropylene is 2 the clinical standard on the case, on the treatment of 3 urinary stress incontinence.</p> <p>4 Q. I understand that. I'm asking -- my 5 question is different, that no society has said that, 6 that use of Ultrapro as a mesh sling would not be safer 7 than the current design?</p> <p>8 A. They have not recommended it, and they 9 have not said that it's safer.</p> <p>10 Q. So that's not really a reason because 11 they haven't said one way or the other, correct?</p> <p>12 A. As surgeons, we also follow the 13 recommendations of the societies.</p> <p>14 Q. I know, but the society has made no 15 assertion one way or the other, so there's nothing to 16 follow.</p> <p>17 A. I'm not saying the society, I'm saying 18 the societies, the clinical societies.</p> <p>19 Q. I understand, you're talking about AUGS 20 and ACOG and --</p> <p>21 A. Right.</p> <p>22 Q. And they have just not spoken to it, 23 correct?</p> <p>24 A. That's correct.</p> <p>25 Q. Okay, so that's not a reason for it or a</p>	

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<p>Page 314</p>	<p>Page 316</p> <p>1 whether or not polypropylene mesh degrades?</p> <p>2 A. I may be asked questions about it. I</p> <p>3 think I have testified already last week on, on, on the</p> <p>4 degradation of polypropylene.</p> <p>5 Q. But you're not a polymer scientist?</p> <p>6 A. No, I'm not a polymer scientist.</p> <p>7 Q. And there are others that are more</p> <p>8 qualified than you to testify about whether or not</p> <p>9 polypropylene degrades?</p> <p>10 A. I think that as a surgeon, there is a</p> <p>11 very limited information that we can give about</p> <p>12 degradation.</p> <p>13 Q. And that would be including yourself?</p> <p>14 A. Yes, we don't have that information one</p> <p>15 way or the other.</p> <p>16 MR. GOSS: Thank you, Doctor.</p> <p>17 CROSS EXAMINATION</p> <p>18 BY MR. FREESE:</p> <p>19 Q. Dr. Sepulveda, we were talking briefly</p> <p>20 about the particle loss. Remember the discussion we</p> <p>21 had about Jennifer's TVTO sling, and you said Dr. Reyes</p> <p>22 reported he didn't see any particles. Do you remember</p> <p>23 that discussion?</p> <p>24 A. Yes.</p> <p>25 Q. Is the phrase linting the same thing as</p>
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